

US3572330 (Prod: Laguna Clinical Research Associates)

Generated By: KC Joubran

Generated On: 10 Jun 2021 08:21:46

All time stamps listed in this document are displayed in GMT

US3572330

Form: Participant Creation

Data signed: (b) (4) 03 Apr 2021 05:07:33

Generated On: 10 Jun 2021 08:21:46

Participant ID

US3572330

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

US3572330

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 22 Mar 2021 03:45:24

Generated On: 10 Jun 2021 08:21:46

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

US3572330

Folder: Screening

Form: Demographics

Data signed: (b) (4) 22 Mar 2021 03:45:23

Generated On: 10 Jun 2021 08:21:46

| | |
|---|--|
| Date of Birth (MMM yyyy) | (b) (6) 1982 |
| Age | 38 |
| Age Units | YEARS |
| Age (Derived) | 38 |
| Sex | Female <input type="radio"/> Male <input checked="" type="radio"/> |
| Ethnicity | Hispanic or Latino <input checked="" type="radio"/> Not Hispanic or Latino <input type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/> |
| Race (Check All That Apply) | |
| White | True |
| Black | False |
| Asian | False |
| American Indian or Alaska Native | False |
| Native Hawaiian or other Pacific Islander | False |
| Other | False |
| If race is Other, specify _____ | |
| Unknown | False |
| Not reported | False |

US3572330

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 22 Mar 2021 03:45:23

Generated On: 10 Jun 2021 08:21:46

| | |
|---|--|
| Date of Informed Consent (<i>dd MMM yyyy</i>) | 21 SEP 2020 |
| Month and Year of Informed Consent (derived) | SEP 2020 |
| Year of Informed Consent (derived) | 2020 |
| Protocol Version | Amendment 1 <input type="radio"/> Amendment 2 <input type="radio"/> Amendment 3 <input checked="" type="radio"/> Amendment 4 <input type="radio"/> Amendment 5 <input type="radio"/> |
| Was participant enrolled in the study? | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| If No, indicate reason for screen fail | Withdrew Consent <input type="radio"/> Inclusion/Exclusion <input type="radio"/> Cohort Full <input type="radio"/> Other <input type="radio"/> |
| If reason for screen fail is Other, specify | |
| Was this participant screened previously? | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| If Yes, previous participant number | |
| Enrollment Trigger | 1 |

US3572330

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 22 Mar 2021 03:45:23

Generated On: 10 Jun 2021 08:21:46

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3572330

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 22 Mar 2021 03:45:24

Generated On: 10 Jun 2021 08:21:46

Were any significant conditions reported?

Yes ☒

No ☐

US3572330

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 22 Mar 2021 03:45:24

Generated On: 10 Jun 2021 08:21:46

| | |
|---|--|
| Condition | HYPERTENSION |
| Start date (dd MMM yyyy) | 01 JAN 2019 |
| 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 2019 |
| Start Year (derived) | 2019 |
| Stop Month and Year (derived) | _____ |
| Stop Year (derived) | _____ |

US3572330

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 22 Mar 2021 03:45:24

Generated On: 10 Jun 2021 08:21:46

| | |
|-------------------------------------|--------------------------------------|
| Were vital signs assessed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Date of assessment (dd MMM yyyy) | 21 SEP 2020 |
| Time of assessment (00:00-23:59) | 10:28 (24 HR) |
| Vital Signs Date and Time (derived) | 21 SEP 2020 10:28 |
| Height (xxx.x) | 70 in |
| Weight (xxx.x) | 270 lb |
| BMI (xxx.x) | 38.82197 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 type="radio"/> |
| If Other, specify | |
| Pulse (xxx) | ND - Not Done |
| Pulse units | BPM |
| Respiratory Rate (xxx) | ND - Not Done |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | ND - Not Done |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | ND - Not Done |
| Diastolic Blood Pressure units | MMHG |
| Height (derived) | |
| Weight (derived) | |

US3572330

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 22 Mar 2021 03:45:24

Generated On: 10 Jun 2021 08:21:46

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

21 SEP 2020

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

US3572330

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 22 Mar 2021 03:45:24

Generated On: 10 Jun 2021 08:21:46

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

US3572330

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 22 Mar 2021 03:45:24

Generated On: 10 Jun 2021 08:21:46

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

US3572330

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 21 Mar 2021 00:25:09

Generated On: 10 Jun 2021 08:21:46

| | |
|---|---|
| Was this visit performed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Visit date (dd MMM yyyy) | 21 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 | VISIT1 |

US3572330

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 21 Mar 2021 00:25:09

Generated On: 10 Jun 2021 08:21:46

What was the date of randomization? (dd MMM yyyy) 21 SEP 2020

What was the participant's randomization number? 114434

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 ☒

US3572330

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 21 Mar 2021 00:25:09

Generated On: 10 Jun 2021 08:21:46

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

US3572330

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 21 Mar 2021 00:25:09

Generated On: 10 Jun 2021 08:21:46

| | |
|-------------------------------------|--|
| 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) | 21 SEP 2020 |
| Time of assessment (00:00-23:59) | 10:33 (24 HR) |
| Vital Signs Date and Time (derived) | 21 SEP 2020 10:33 |
| Temperature (xxx.x) | 97.7 F |
| Route of measurement | Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/> |
| If Other, specify | TEMPORAL |
| Pulse (xxx) | 90 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 18 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 124 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 93 mmHg |
| Diastolic Blood Pressure units | MMHG |

US3572330

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 21 Mar 2021 00:25:09

Generated On: 10 Jun 2021 08:21:46

| | |
|-------------------------------------|--|
| 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) | 21 SEP 2020 |
| Time of assessment (00:00-23:59) | 11:52 (24 HR) |
| Vital Signs Date and Time (derived) | 21 SEP 2020 11:52 |
| Temperature (xxx.x) | 97.8 F |
| Route of measurement | Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/> |
| If Other, specify | TEMPORAL |
| Pulse (xxx) | 62 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 18 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 136 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 86 mmHg |
| Diastolic Blood Pressure units | MMHG |

US3572330

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 21 Mar 2021 00:25:09

Generated On: 10 Jun 2021 08:21:46

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.

US3572330

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 21 Mar 2021 00:25:09

Generated On: 10 Jun 2021 08:21:46

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) 21 SEP 2020

What was the treatment time? (00:00-23:59) 11:22 (24 HR)

Treatment Date and Time (derived) 21 SEP 2020 11:22

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

What was the frequency of the study treatment dosing? ONCE

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

US3572330

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 21 Mar 2021 00:25:09

Generated On: 10 Jun 2021 08:21:46

| | |
|------------------------------------|--------------------------------------|
| Was the sample collected? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Collection date (dd MMM yyyy) | 21 SEP 2020 |
| Collection time (00:00-23:59) | 10:44 (24 HR) |
| Collection date and time (derived) | 21 SEP 2020 10:44 |

US3572330

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 21 Mar 2021 00:25:09

Generated On: 10 Jun 2021 08:21:46

| | | | |
|-------------------------------|---------------------------|---------------------------------|------------------------------------|
| Collection date (dd MMM yyyy) | | | 21 SEP 2020 |
| Lab Test | Was the sample collected? | Collection time (00:00 - 23:59) | Collection date and time (derived) |
| Nasopharyngeal Swab 1 | Yes | 10:06 | 21 SEP 2020 10:06 |
| Nasopharyngeal Swab 2 | No | | |

US3572330

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 21 Mar 2021 00:25:09

Generated On: 10 Jun 2021 08:21:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3572330

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:21:46

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

97.3 °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

21 SEP 2020 12:02

PC Open Date & Time

21 SEP 2020 11:42

PC Close Date & Time

21 SEP 2020 14:12

US3572330

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:21:46

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 99.1 °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 SEP 2020 19:06 |
| PC Open Date & Time | 21 SEP 2020 15:07 |
| PC Close Date & Time | 22 SEP 2020 11:59 |

US3572330

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:21:46

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

99.6 °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

22 SEP 2020 22:05

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3572330

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:21:46

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

99.1 °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

23 SEP 2020 21:38

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3572330

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:21:46

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

99.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

24 SEP 2020 19:45

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3572330

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

26 SEP 2020 10:59

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3572330

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:21:46

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

98.6 °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

26 SEP 2020 19:35

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3572330

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:21:46

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

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3572330

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:21:46

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

21 SEP 2020 12:03

PC Open Date & Time

21 SEP 2020 11:42

PC Close Date & Time

21 SEP 2020 14:12

US3572330

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:21:46

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

21 SEP 2020 19:07

PC Open Date & Time

21 SEP 2020 15:07

PC Close Date & Time

22 SEP 2020 11:59

US3572330

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☒

No ☐

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

30

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

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

Yes ☒

No ☐

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

30

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

22 SEP 2020 16:36

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3572330

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☒

No ☐

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

30

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

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

Yes ☒

No ☐

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

30

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

23 SEP 2020 21:36

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3572330

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:21:46

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 ☐

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

20

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

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

Yes ☒

No ☐

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

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

24 SEP 2020 19:45

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3572330

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:21:46

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 ☐

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

10

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

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

26 SEP 2020 11:00

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3572330

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:21:46

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

26 SEP 2020 19:36

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3572330

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:21:46

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 ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3572330

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:21:46

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 ☐

US3572330

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:21:46

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

No ☒

Yes ☐

| | |
|----------------------|-------------------|
| PC Time stamp | 21 SEP 2020 12:05 |
| PC Open Date & Time | 21 SEP 2020 11:42 |
| PC Close Date & Time | 21 SEP 2020 14:12 |

US3572330

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:21:46

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 ☐

US3572330

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:21:46

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

No ☒

Yes ☐

| | |
|----------------------|-------------------|
| PC Time stamp | 21 SEP 2020 19:08 |
| PC Open Date & Time | 21 SEP 2020 15:07 |
| PC Close Date & Time | 22 SEP 2020 11:59 |

US3572330

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:21:46

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

42 of 1696

EAB) (1725)

US3572330

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:21:46

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 22 SEP 2020 16:36 |
| PC Open Date & Time | 22 SEP 2020 12:00 |
| PC Close Date & Time | 23 SEP 2020 11:59 |

US3572330

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:21:46

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

44 of 1696

EAB) (1725)

US3572330

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:21:46

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 23 SEP 2020 21:35 |
| PC Open Date & Time | 23 SEP 2020 12:00 |
| PC Close Date & Time | 24 SEP 2020 11:59 |

US3572330

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

46 of 1696

US3572330

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:21:46

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 24 SEP 2020 19:46 |
| PC Open Date & Time | 24 SEP 2020 12:00 |
| PC Close Date & Time | 25 SEP 2020 11:59 |

US3572330

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:21:46

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

48 of 1696

EAB) (1725)

US3572330

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:21:46

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

US3572330

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:21:46

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

50 of 1696

EAB) (1725)

US3572330

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:21:46

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 26 SEP 2020 19:36 |
| PC Open Date & Time | 26 SEP 2020 12:00 |
| PC Close Date & Time | 27 SEP 2020 11:59 |

US3572330

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:21:46

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 ☐

US3572330

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:21:46

Yes ☐

PC Time stamp

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3572330

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

28 SEP 2020 14:51

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3572330

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3572330

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

DAY 10

Select one response below to indicate the intensity of your

None ☒

FATIGUE

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

30 SEP 2020 14:11

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3572330

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 08:21:46

| | |
|---|--|
| TIMEPOINT | DAY 8 |
| Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| PC Time stamp | 28 SEP 2020 14:51 |
| PC Open Date & Time | 28 SEP 2020 12:00 |
| PC Close Date & Time | 29 SEP 2020 11:59 |

US3572330

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 08:21:46

| | |
|---|------------------------------|
| TIMEPOINT | DAY 9 |
| Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms? | No <input type="checkbox"/> |
| | Yes <input type="checkbox"/> |
| PC Time stamp | |
| PC Open Date & Time | 29 SEP 2020 12:00 |
| PC Close Date & Time | 30 SEP 2020 11:59 |

US3572330

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 10 Jun 2021 08:21:46

| | |
|---|--|
| TIMEPOINT | DAY 10 |
| Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| PC Time stamp | 30 SEP 2020 14:11 |
| PC Open Date & Time | 30 SEP 2020 12:00 |
| PC Close Date & Time | 01 OCT 2020 11:59 |

US3572330

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 21 Mar 2021 00:25:09

Generated On: 10 Jun 2021 08:21:46

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3572330

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 21 Mar 2021 00:25:09

Generated On: 10 Jun 2021 08:21:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3572330

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 21 Mar 2021 00:25:09

Generated On: 10 Jun 2021 08:21:46

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

6 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3572330

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 21 Mar 2021 00:25:09

Generated On: 10 Jun 2021 08:21:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3572330

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 21 Mar 2021 00:25:09

Generated On: 10 Jun 2021 08:21:46

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

US3572330

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 21 Mar 2021 00:25:09

Generated On: 10 Jun 2021 08:21:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3572330

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 21 Mar 2021 00:25:09

Generated On: 10 Jun 2021 08:21:46

| | |
|---|---|
| Was this visit performed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Visit date (dd MMM yyyy) | 26 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 | VISIT2 |

US3572330

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 21 Mar 2021 00:25:09

Generated On: 10 Jun 2021 08:21:46

| | |
|-------------------------------------|---|
| 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) | 26 OCT 2020 |
| Time of assessment (00:00-23:59) | 09:00 (24 HR) |
| Vital Signs Date and Time (derived) | 26 OCT 2020 09:00 |
| Temperature (xxx.x) | 97.7 F |
| Route of measurement | Oral <input type="radio"/> |
| | Axillary <input type="radio"/> |
| | Other <input checked="" type="radio"/> |
| If Other, specify | TEMPORAL |
| Pulse (xxx) | 70 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 20 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 144 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 87 mmHg |
| Diastolic Blood Pressure units | MMHG |

US3572330

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 21 Mar 2021 00:25:09

Generated On: 10 Jun 2021 08:21:46

| | |
|-------------------------------------|--|
| 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) | 26 OCT 2020 |
| Time of assessment (00:00-23:59) | 10:08 (24 HR) |
| Vital Signs Date and Time (derived) | 26 OCT 2020 10:08 |
| Temperature (xxx.x) | 97.3 F |
| Route of measurement | Oral <input type="radio"/> |
| | Axillary <input type="radio"/> |
| | Other <input checked="" type="radio"/> |
| If Other, specify | TEMPORAL |
| Pulse (xxx) | 72 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | ND - Not Done |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 134 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 89 mmHg |
| Diastolic Blood Pressure units | MMHG |

US3572330

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 21 Mar 2021 00:25:09

Generated On: 10 Jun 2021 08:21:46

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

26 OCT 2020

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

US3572330

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 21 Mar 2021 00:25:09

Generated On: 10 Jun 2021 08:21:46

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 26 OCT 2020

What was the treatment time? (00:00-23:59) 09:38 (24 HR)

Treatment Date and Time (derived) 26 OCT 2020 09:38

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

US3572330

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 21 Mar 2021 00:25:09

Generated On: 10 Jun 2021 08:21:46

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

26 OCT 2020

Collection time (00:00-23:59)

09:13 (24 HR)

Collection date and time (derived)

26 OCT 2020 09:13

US3572330

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 21 Mar 2021 00:25:09

Generated On: 10 Jun 2021 08:21:46

| | | | |
|-------------------------------|---------------------------|---------------------------------|------------------------------------|
| Collection date (dd MMM yyyy) | | | 26 OCT 2020 |
| Lab Test | Was the sample collected? | Collection time (00:00 - 23:59) | Collection date and time (derived) |
| Nasopharyngeal Swab 1 | Yes | 09:08 | 26 OCT 2020 09:08 |
| Nasopharyngeal Swab 2 | No | | |

US3572330

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 21 Mar 2021 00:25:09

Generated On: 10 Jun 2021 08:21:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3572330

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:21:46

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

97.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

26 OCT 2020 10:14

PC Open Date & Time

26 OCT 2020 09:58

PC Close Date & Time

26 OCT 2020 12:28

US3572330

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:21:46

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 98.6 °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 | 27 OCT 2020 00:12 |
| PC Open Date & Time | 26 OCT 2020 13:23 |
| PC Close Date & Time | 27 OCT 2020 11:59 |

US3572330

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

27 OCT 2020 23:27

PC Open Date & Time

27 OCT 2020 12:00

PC Close Date & Time

28 OCT 2020 11:59

US3572330

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

29 OCT 2020 11:51

PC Open Date & Time

28 OCT 2020 12:00

PC Close Date & Time

29 OCT 2020 11:59

US3572330

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

29 OCT 2020 22:26

PC Open Date & Time

29 OCT 2020 12:00

PC Close Date & Time

30 OCT 2020 11:59

US3572330

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:21:46

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

97.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

30 OCT 2020 22:10

PC Open Date & Time

30 OCT 2020 12:00

PC Close Date & Time

31 OCT 2020 11:59

US3572330

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:21:46

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

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

31 OCT 2020 12:00

PC Close Date & Time

01 NOV 2020 11:59

US3572330

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:21:46

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

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

01 NOV 2020 12:00

PC Close Date & Time

02 NOV 2020 11:59

US3572330

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

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

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

Please select one response below

None ☐

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

26 OCT 2020 10:14

PC Open Date & Time

26 OCT 2020 09:58

PC Close Date & Time

26 OCT 2020 12:28

US3572330

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

26 OCT 2020 20:17

PC Open Date & Time

26 OCT 2020 13:23

PC Close Date & Time

27 OCT 2020 11:59

US3572330

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

27 OCT 2020 23:28

PC Open Date & Time

27 OCT 2020 12:00

PC Close Date & Time

28 OCT 2020 11:59

US3572330

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

29 OCT 2020 11:52

PC Open Date & Time

28 OCT 2020 12:00

PC Close Date & Time

29 OCT 2020 11:59

US3572330

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

29 OCT 2020 22:27

PC Open Date & Time

29 OCT 2020 12:00

PC Close Date & Time

30 OCT 2020 11:59

US3572330

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

30 OCT 2020 22:09

PC Open Date & Time

30 OCT 2020 12:00

PC Close Date & Time

31 OCT 2020 11:59

US3572330

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:21:46

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 ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

31 OCT 2020 12:00

PC Close Date & Time

01 NOV 2020 11:59

US3572330

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:21:46

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 ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

01 NOV 2020 12:00

PC Close Date & Time

02 NOV 2020 11:59

US3572330

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:21:46

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 ☐

US3572330

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:21:46

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

No ☒

Yes ☐

| | |
|----------------------|-------------------|
| PC Time stamp | 26 OCT 2020 10:15 |
| PC Open Date & Time | 26 OCT 2020 09:58 |
| PC Close Date & Time | 26 OCT 2020 12:28 |

US3572330

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:21:46

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 ☐

US3572330

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:21:46

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

No ☒

Yes ☐

| | |
|----------------------|-------------------|
| PC Time stamp | 26 OCT 2020 20:17 |
| PC Open Date & Time | 26 OCT 2020 13:23 |
| PC Close Date & Time | 27 OCT 2020 11:59 |

US3572330

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:21:46

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

94 of 1696

EAB) (1725)

US3572330

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:21:46

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 27 OCT 2020 23:28 |
| PC Open Date & Time | 27 OCT 2020 12:00 |
| PC Close Date & Time | 28 OCT 2020 11:59 |

US3572330

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:21:46

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

96 of 1696

EAB) (1725)

US3572330

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:21:46

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 29 OCT 2020 11:52 |
| PC Open Date & Time | 28 OCT 2020 12:00 |
| PC Close Date & Time | 29 OCT 2020 11:59 |

US3572330

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

DAY 4

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

98 of 1696

EAB) (1725)

US3572330

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:21:46

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 29 OCT 2020 22:27 |
| PC Open Date & Time | 29 OCT 2020 12:00 |
| PC Close Date & Time | 30 OCT 2020 11:59 |

US3572330

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

100 of 1696

US3572330

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:21:46

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 30 OCT 2020 22:09 |
| PC Open Date & Time | 30 OCT 2020 12:00 |
| PC Close Date & Time | 31 OCT 2020 11:59 |

US3572330

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:21:46

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 ☐

US3572330

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:21:46

Yes ☐

PC Time stamp

PC Open Date & Time

31 OCT 2020 12:00

PC Close Date & Time

01 NOV 2020 11:59

US3572330

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

DAY 7

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

104 of 1696

US3572330

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:21:46

Yes ☐

PC Time stamp

PC Open Date & Time

01 NOV 2020 12:00

PC Close Date & Time

02 NOV 2020 11:59

US3572330

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 21 Mar 2021 00:25:09

Generated On: 10 Jun 2021 08:21:46

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

2 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3572330

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 21 Mar 2021 00:25:09

Generated On: 10 Jun 2021 08:21:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3572330

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 21 Mar 2021 00:25:09

Generated On: 10 Jun 2021 08:21:46

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

9 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3572330

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 21 Mar 2021 00:25:09

Generated On: 10 Jun 2021 08:21:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3572330

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 21 Mar 2021 00:25:09

Generated On: 10 Jun 2021 08:21:46

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 16 NOV 2020

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

Comments

If Contact Not Made, please provide Comments

US3572330

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 21 Mar 2021 00:25:09

Generated On: 10 Jun 2021 08:21:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3572330

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 21 Mar 2021 00:25:09

Generated On: 10 Jun 2021 08:21:46

| | |
|---|---|
| Was this visit performed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Visit date (dd MMM yyyy) | 20 NOV 2020 |
| Was visit performed at the participant's home or at the clinic? | Home <input type="radio"/> |
| | Clinic <input checked="" type="radio"/> |
| Folder OID | VISIT3 |

US3572330

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 21 Mar 2021 00:25:09

Generated On: 10 Jun 2021 08:21:46

| | |
|-------------------------------------|--|
| Were vital signs assessed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Date of assessment (dd MMM yyyy) | 20 NOV 2020 |
| Time of assessment (00:00-23:59) | 09:50 (24 HR) |
| Vital Signs Date and Time (derived) | 20 NOV 2020 09:50 |
| Temperature (xxx.x) | 97.7 F |
| Route of measurement | Oral <input type="radio"/> |
| | Axillary <input type="radio"/> |
| | Other <input checked="" type="radio"/> |
| If Other, specify | TEMPORAL |
| Pulse (xxx) | 79 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 20 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 139 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 85 mmHg |
| Diastolic Blood Pressure units | MMHG |
| Height (derived) | |
| Weight (derived) | |

US3572330

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 21 Mar 2021 00:25:09

Generated On: 10 Jun 2021 08:21:46

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

20 NOV 2020

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

US3572330

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 21 Mar 2021 00:25:09

Generated On: 10 Jun 2021 08:21:46

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

20 NOV 2020

Collection time (00:00-23:59)

10:13 (24 HR)

Collection date and time (derived)

20 NOV 2020 10:13

US3572330

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 21 Mar 2021 00:25:09

Generated On: 10 Jun 2021 08:21:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

| TIMEPOINT | DAY 61 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> 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"/> |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

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

[Patient Cloud Close Date & Time](#)

22 NOV 2020 23:59

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

| | |
|---|--|
| TIMEPOINT | DAY 68 |
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Date and time of submission | 25 NOV 2020 16:28:22 |
| Patient Cloud Open Date & Time | 25 NOV 2020 00:01 |
| Patient Cloud Close Date & Time | 29 NOV 2020 23:59 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

| TIMEPOINT | DAY 75 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> 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"/> |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

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

[Patient Cloud Close Date & Time](#)

06 DEC 2020 23:59

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

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

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

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

[Patient Cloud Close Date & Time](#)

13 DEC 2020 23:59

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

| | |
|---|--|
| TIMEPOINT | DAY 89 |
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Date and time of submission | 19 DEC 2020 20:16:13 |
| Patient Cloud Open Date & Time | 16 DEC 2020 00:01 |
| Patient Cloud Close Date & Time | 20 DEC 2020 23:59 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

| 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"/> |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

27 DEC 2020 23:59

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

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

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

03 JAN 2021 23:59

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

| TIMEPOINT | DAY 110 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Date and time of submission | 07 JAN 2021 11:43:21 |
| Patient Cloud Open Date & Time | 06 JAN 2021 00:01 |
| Patient Cloud Close Date & Time | 10 JAN 2021 23:59 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

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

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

17 JAN 2021 23:59

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

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

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

24 JAN 2021 23:59

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

| TIMEPOINT | DAY 131 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input 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"/> |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

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

| | |
|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 27 JAN 2021 00:01 |
| Patient Cloud Close Date & Time | 31 JAN 2021 23:59 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

DAY 138

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

07 FEB 2021 23:59

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

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

10 FEB 2021 00:06:55

Patient Cloud Open Date & Time

10 FEB 2021 00:01

Patient Cloud Close Date & Time

14 FEB 2021 23:59

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

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

21 FEB 2021 19:51:36

Patient Cloud Open Date & Time

17 FEB 2021 00:01

Patient Cloud Close Date & Time

21 FEB 2021 23:59

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

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

27 FEB 2021 19:46:19

Patient Cloud Open Date & Time

24 FEB 2021 00:01

Patient Cloud Close Date & Time

28 FEB 2021 23:59

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

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

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

07 MAR 2021 23:59

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

DAY 173

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

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

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

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

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

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

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 ☐

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

14 MAR 2021 23:59

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

| TIMEPOINT | DAY 180 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

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

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 MAR 2021 01:51:11

Patient Cloud Open Date & Time

24 MAR 2021 00:01

Patient Cloud Close Date & Time

28 MAR 2021 23:59

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

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

31 MAR 2021 00:01:42

Patient Cloud Open Date & Time

31 MAR 2021 00:01

Patient Cloud Close Date & Time

04 APR 2021 23:59

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

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 APR 2021 00:01:42

Patient Cloud Open Date & Time

07 APR 2021 00:01

Patient Cloud Close Date & Time

11 APR 2021 23:59

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

15 APR 2021 22:14:24

Patient Cloud Open Date & Time

14 APR 2021 00:01

Patient Cloud Close Date & Time

18 APR 2021 23:59

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

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

21 APR 2021 09:18:01

Patient Cloud Open Date & Time

21 APR 2021 00:01

Patient Cloud Close Date & Time

25 APR 2021 23:59

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

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

02 MAY 2021 10:43:45

Patient Cloud Open Date & Time

28 APR 2021 00:01

Patient Cloud Close Date & Time

02 MAY 2021 23:59

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

DAY 229

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

09 MAY 2021 23:59

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

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

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

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

[Patient Cloud Close Date & Time](#)

16 MAY 2021 23:59

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

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

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

23 MAY 2021 23:59

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

| TIMEPOINT | DAY 250 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> 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"/> |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

30 MAY 2021 23:59

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

DAY 257

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

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

[Patient Cloud Close Date & Time](#)

06 JUN 2021 23:59

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

| TIMEPOINT | DAY 264 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

13 JUN 2021 23:59

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

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

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

20 JUN 2021 23:59

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

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

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

27 JUN 2021 23:59

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

| TIMEPOINT | DAY 285 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

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

| | |
|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 30 JUN 2021 00:01 |
| Patient Cloud Close Date & Time | 04 JUL 2021 23:59 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

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 ☐ 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 ☐

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

11 JUL 2021 23:59

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

DAY 299

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

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

[Patient Cloud Close Date & Time](#)

18 JUL 2021 23:59

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

| TIMEPOINT | DAY 306 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <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"/> |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

25 JUL 2021 23:59

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

| TIMEPOINT | DAY 313 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> 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"/> |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

01 AUG 2021 23:59

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

| TIMEPOINT | DAY 320 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

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

[Patient Cloud Close Date & Time](#)

08 AUG 2021 23:59

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

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 ☐

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

15 AUG 2021 23:59

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

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

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

22 AUG 2021 23:59

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

| TIMEPOINT | DAY 341 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> 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"/> |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

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

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

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

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

05 SEP 2021 23:59

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

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 ☐

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

12 SEP 2021 23:59

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

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

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 ☐

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 SEP 2021 00:01 |
| Patient Cloud Close Date & Time | 19 SEP 2021 23:59 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

DAY 369

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

26 SEP 2021 23:59

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

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 ☐

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

03 OCT 2021 23:59

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

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 ☐

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

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

[Patient Cloud Close Date & Time](#)

10 OCT 2021 23:59

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

| 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"/> |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

17 OCT 2021 23:59

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

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 ☐

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

24 OCT 2021 23:59

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

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

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

31 OCT 2021 23:59

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

| 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"/> |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

07 NOV 2021 23:59

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

| 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"/> |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

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

[Patient Cloud Close Date & Time](#)

14 NOV 2021 23:59

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

| TIMEPOINT | DAY 425 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

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

[Patient Cloud Close Date & Time](#)

21 NOV 2021 23:59

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

DAY 432

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

28 NOV 2021 23:59

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

| 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"/> |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

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

[Patient Cloud Close Date & Time](#)

05 DEC 2021 23:59

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

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

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

12 DEC 2021 23:59

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

| TIMEPOINT | DAY 453 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

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

[Patient Cloud Close Date & Time](#)

19 DEC 2021 23:59

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

| TIMEPOINT | DAY 460 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

26 DEC 2021 23:59

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

| TIMEPOINT | DAY 467 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> 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"/> |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

02 JAN 2022 23:59

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

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 ☐

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

09 JAN 2022 23:59

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

| TIMEPOINT | DAY 481 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

16 JAN 2022 23:59

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

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

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

23 JAN 2022 23:59

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

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 ☐

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

30 JAN 2022 23:59

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

DAY 502

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

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

[Patient Cloud Close Date & Time](#)

06 FEB 2022 23:59

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

DAY 509

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

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

[Patient Cloud Close Date & Time](#)

13 FEB 2022 23:59

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

| TIMEPOINT | DAY 516 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

20 FEB 2022 23:59

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

| 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"/> |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

27 FEB 2022 23:59

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

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 ☐

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

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

[Patient Cloud Close Date & Time](#)

06 MAR 2022 23:59

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

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) | <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 ☐

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 ☐

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

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

[Patient Cloud Close Date & Time](#)

13 MAR 2022 23:59

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

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

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

20 MAR 2022 23:59

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

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 ☐

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

27 MAR 2022 23:59

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

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 ☐

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

03 APR 2022 23:59

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

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 ☐

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

10 APR 2022 23:59

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

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 ☐

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

17 APR 2022 23:59

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

DAY 579

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

24 APR 2022 23:59

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

01 MAY 2022 23:59

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

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 ☐

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

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

[Patient Cloud Close Date & Time](#)

08 MAY 2022 23:59

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

| 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"/> |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

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

[Patient Cloud Close Date & Time](#)

15 MAY 2022 23:59

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

| TIMEPOINT | DAY 607 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

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

[Patient Cloud Close Date & Time](#)

22 MAY 2022 23:59

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

| 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"/> |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

29 MAY 2022 23:59

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

| TIMEPOINT | DAY 621 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JUN 2022 23:59

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

DAY 628

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JUN 2022 23:59

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

| TIMEPOINT | DAY 635 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

19 JUN 2022 23:59

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

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 ☐

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

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

| | |
|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 22 JUN 2022 00:01 |
| Patient Cloud Close Date & Time | 26 JUN 2022 23:59 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

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 ☐

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

03 JUL 2022 23:59

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

| TIMEPOINT | DAY 656 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

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

[Patient Cloud Close Date & Time](#)

10 JUL 2022 23:59

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

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 ☐

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

17 JUL 2022 23:59

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

| TIMEPOINT | DAY 670 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

24 JUL 2022 23:59

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

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 ☐

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

31 JUL 2022 23:59

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

| TIMEPOINT | DAY 684 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

07 AUG 2022 23:59

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

| TIMEPOINT | DAY 691 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> 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"/> |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

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

[Patient Cloud Close Date & Time](#)

14 AUG 2022 23:59

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

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 ☐

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

21 AUG 2022 23:59

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

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 ☐

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

28 AUG 2022 23:59

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

| TIMEPOINT | DAY 712 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <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"/> |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

04 SEP 2022 23:59

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

| 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"/> |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 SEP 2022 00:01 |
| Patient Cloud Close Date & Time | 11 SEP 2022 23:59 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

| 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"/> |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

18 SEP 2022 23:59

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

DAY 733

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

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

[Patient Cloud Close Date & Time](#)

25 SEP 2022 23:59

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

| TIMEPOINT | DAY 740 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

02 OCT 2022 23:59

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

| 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"/> |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

09 OCT 2022 23:59

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

| TIMEPOINT | DAY 754 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> 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"/> |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

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

| | |
|---|-------------------|
| Patient Cloud Close Date & Time | 16 OCT 2022 23:59 |
|---|-------------------|

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

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 ☐

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

23 OCT 2022 23:59

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

| TIMEPOINT | DAY 768 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

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

| | |
|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 26 OCT 2022 00:01 |
| Patient Cloud Close Date & Time | 30 OCT 2022 23:59 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

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 ☐

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

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

[Patient Cloud Close Date & Time](#)

06 NOV 2022 23:59

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

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 ☐

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

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

[Patient Cloud Close Date & Time](#)

13 NOV 2022 23:59

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

DAY 789

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

20 NOV 2022 23:59

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

| 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"/> |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

27 NOV 2022 23:59

US3572330

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 10 Jun 2021 08:21:46

| 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 | | 27 FEB 2021 19:46:07 |

US3572330

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 21 Mar 2021 04:25:17

Generated On: 10 Jun 2021 08:21:46

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3572330

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 21 Mar 2021 04:25:17

Generated On: 10 Jun 2021 08:21:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3572330

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 03 Apr 2021 05:07:34

Generated On: 10 Jun 2021 08:21:46

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

26 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3572330

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 03 Apr 2021 05:07:34

Generated On: 10 Jun 2021 08:21:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3572330

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 03 Apr 2021 05:07:34

Generated On: 10 Jun 2021 08:21:46

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3572330

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 03 Apr 2021 05:07:34

Generated On: 10 Jun 2021 08:21:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3572330

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 03 Apr 2021 05:07:34

Generated On: 10 Jun 2021 08:21:46

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3572330

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 03 Apr 2021 05:07:34

Generated On: 10 Jun 2021 08:21:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3572330

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 03 May 2021 15:01:42

Generated On: 10 Jun 2021 08:21:46

| | |
|---|---|
| Was this visit performed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Visit date (dd MMM yyyy) | 27 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 | VISIT4 |

US3572330

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 03 May 2021 15:01:42

Generated On: 10 Jun 2021 08:21:46

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) _____

US3572330

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 03 May 2021 15:01:42

Generated On: 10 Jun 2021 08:21:46

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.

US3572330

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 03 May 2021 15:01:42

Generated On: 10 Jun 2021 08:21:46

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

27 APR 2021

Collection time (00:00-23:59)

10:14 (24 HR)

Collection date and time (derived)

27 APR 2021 10:14

US3572330

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 03 May 2021 15:01:42

Generated On: 10 Jun 2021 08:21:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3572330

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:21:46

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

US3572330

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:21:46

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3572330

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:21:46

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

US3572330

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 10 Jun 2021 08:21:46

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3572330

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

Form: Visit Date

Data signed: (b) (4) 03 Apr 2021 05:07:33

Generated On: 10 Jun 2021 08:21:46

Was this visit performed? Yes ☐
No ☒

Visit date (dd MMM yyyy)

Was visit performed at the participant's home or at the clinic? Home ☐
Clinic ☐

Folder OID UNBLND_DECIDE

US3572330

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

Form: Unblinding

Data signed: (b) (4) 15 Apr 2021 19:17:23

Generated On: 10 Jun 2021 08:21:46

| | |
|---|---|
| Date of updated informed consent (<i>dd MMM yyyy</i>) | |
| N/A - Subject Unblinded under Amendment 5 and Discontinued from Study | True |
| Was the participant unblinded? | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Under what version of the Protocol was the Participant unblinded? | Amendment 5 <input checked="" type="radio"/> Amendment 6 or later <input type="radio"/> |
| Date of unblinding (<i>dd MMM yyyy</i>) | 18 DEC 2020 |
| Participant randomization assignment | mRNA-1273 <input checked="" type="radio"/> Placebo <input type="radio"/> |
| Actual Dose 1 | mRNA-1273 <input checked="" type="radio"/> Placebo <input type="radio"/> Not Administered <input type="radio"/> |
| Actual Dose 2 | mRNA-1273 <input checked="" type="radio"/> Placebo <input type="radio"/> Not Administered <input type="radio"/> |
| Will participant receive mRNA-1273? | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Placebo Only Flag | |
| Continuing with mRNA-1273 | |

US3572330

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 03 Apr 2021 05:07:33

Generated On: 10 Jun 2021 08:21:46

Was the sample collected?

Yes ☐

No ☒

Collection date (dd MMM yyyy)

Collection time (00:00-23:59)

Collection date and time (derived)

US3572330

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 03 Apr 2021 05:07:33

Generated On: 10 Jun 2021 08:21:46

Was the sample collected?

Yes ☐

No ☒

Collection date (dd MMM yyyy)

Collection time (00:00 - 23:59)

Collection Date and Time (derived)

US3572330

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 13 Apr 2021 04:35:22

Generated On: 10 Jun 2021 08:21:46

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3572330

Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 29 Apr 2021 15:47:47

Generated On: 10 Jun 2021 08:21:46

| | |
|--|--|
| AEID | |
| Adverse event | FATIGUE |
| Was this a medically-attended AE? | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Was this a Solicited Adverse Reaction? | Yes <input checked="" type="radio"/> No <input 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) | 28 SEP 2020 |
| Start time (00:00-23:59) | |
| AE start date and time (derived) | |
| Ongoing? | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| If not Ongoing, end date (dd MMM yyyy) | 3 NOV 2020 |
| End time (00:00-23:59) | |
| AE End Date and Time (derived) | |
| Severity | Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/> |
| Is the adverse event serious? | Yes <input 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 | |

PRODUCTION RELEASE (v12.003
EAB) (1725)

340 of 1696

US3572330

Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 29 Apr 2021 15:47:47

Generated On: 10 Jun 2021 08:21:46

| | |
|---|---|
| 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 | True |
| Concomitant Medication | False |
| Concomitant Procedure | False |
| Outcome | Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/> |
| If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____ | |
| Narrative _____ | |
| Serious Adverse Event Derived (CSA Programming Field Only) | 0 |
| Medically Attended AE Derived (CSA Programming Field Only) | 0 |
| Admitted to ICU Derived (CSA Programming Field Only) | _____ |

US3572330

Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 29 Apr 2021 15:47:47

Generated On: 10 Jun 2021 08:21:46

| | |
|--|--|
| AEID | USA-US091-2021-MRNA-1273-P30 1000021 |
| Adverse event | ELECTIVE GASTRIC BYPASS |
| 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 type="radio"/> No <input checked="" type="radio"/> |
| Start date (dd MMM yyyy) | 16 JAN 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) | 18 JAN 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 checked="" type="radio"/> No <input type="radio"/> |
| AE is serious due To (check all that apply) | |
| Death | False |
| Life threatening | False |
| Requires inpatient or prolongation of existing Hospitalization | True |
| Hospital Admission Date (dd MMM yyyy) | 16 JAN 2021 |
| Hospital Discharge Date (dd MMM yyyy) | 18 JAN 2021 |
| Admitted to ICU? | Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/> |

PRODUCTION RELEASE (v12.003
EAB) (1725)

342 of 1696

US3572330

Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 29 Apr 2021 15:47:47

Generated On: 10 Jun 2021 08:21:46

| | |
|--|---|
| Number of Days in ICU | |
| Persistent or significant disability or incapacity | False |
| Congenital anomaly or birth defect | False |
| Other medically important event | False |
| Relationship to investigational product | Not Related <input checked="" type="radio"/> 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 Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/> |
| Other action taken (check all that apply) | |
| None | True |
| Concomitant Medication | False |
| Concomitant Procedure | False |
| Outcome | Fatal <input type="radio"/> 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 | SUBJECT REPORTED HAVING GASTRIC BYPASS ON 16JAN2021, DISCHARGED FROM HOSPITAL 18JAN2021. UNABLE TO OBTAIN RECORDS, SURGERY PERFORMED IN MONTERREY MEXICO. |
|-----------|---|

US3572330

Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 29 Apr 2021 15:47:47

Generated On: 10 Jun 2021 08:21:46

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

US3572330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 03 Apr 2021 05:07:33

Generated On: 10 Jun 2021 08:21:46

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

Yes ☒

No ☐

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

US3572330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 03 Apr 2021 05:07:33

Generated On: 10 Jun 2021 08:21:46

Name of Medication ANTIBIOTIC (MEXICAN DRUG)

Prophylaxis Yes ☒
No ☐

Indication PROPHYLAXIS PRE-OP FOR
GASTRIC BYPASS SURGERY

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

346 of 1696

US3572330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 03 Apr 2021 05:07:33

Generated On: 10 Jun 2021 08:21:46

| | | |
|--|--------------------------|-------------------------------------|
| | Intraocular | <input type="checkbox"/> |
| | Intramuscular | <input type="checkbox"/> |
| | Respiratory (Inhalation) | <input type="checkbox"/> |
| | Intralesional | <input type="checkbox"/> |
| | Intraperitoneal | <input type="checkbox"/> |
| | Nasal | <input type="checkbox"/> |
| | Vaginal | <input type="checkbox"/> |
| | Rectal | <input type="checkbox"/> |
| | Intravenous | <input type="checkbox"/> |
| | Intravenous Bolus | <input type="checkbox"/> |
| | Intravenous Drip | <input type="checkbox"/> |
| | Other | <input type="checkbox"/> |
| If route of administration is Other, specify | | |
| Start date (dd MMM yyyy) | 15 JAN 2021 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy) | 17 JAN 2021 | |
| Was this medication taken for solicited event? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| Separate Dosage Number (derived) | 2 | |
| Interval Dosage Unit Number (derived) | 1 | |
| Interval Dosage Definition (derived) | 802 | <input type="checkbox"/> |
| | 803 | <input type="checkbox"/> |
| | 804 | <input checked="" type="checkbox"/> |

US3572330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 03 Apr 2021 05:07:33

Generated On: 10 Jun 2021 08:21:46

Name of Medication LOSARTAN

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 50/25

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

348 of 1696

US3572330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 03 Apr 2021 05:07:33

Generated On: 10 Jun 2021 08:21:46

| | | |
|--|--------------------------|----------------------------------|
| | 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) | | 01 JAN 2019 |
| Start date completely unknown | | False |
| Ongoing? | Yes | <input checked="" type="radio"/> |
| | No | <input type="radio"/> |
| If not Ongoing, End date (dd MMM yyyy) _____ | | |
| Was this medication taken for solicited event? | Yes | <input type="radio"/> |
| | No | <input checked="" type="radio"/> |
| Separate Dosage Number (derived) | | 1 |
| Interval Dosage Unit Number (derived) | | 1 |
| Interval Dosage Definition (derived) | 802 | <input type="radio"/> |
| | 803 | <input type="radio"/> |
| | 804 | <input checked="" type="radio"/> |

US3572330

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 03 Apr 2021 05:07:33

Generated On: 10 Jun 2021 08:21:46

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3572330

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 03 Apr 2021 05:07:33

Generated On: 10 Jun 2021 08:21:46

| Procedure/Surgery date (dd MMM yyyy) | Procedure/Surgery | Indication | If indication is Other, specify |
|---|-------------------|------------|---------------------------------|
| 16 JAN 2021 | GASTRIC BYPASS | Other | WEIGHT REDUCTION |

US3572330

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 08:21:46

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

US3572330

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 08:21:46

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 ☐

US3572330

Folder: SAE USA-US091-2021-MRNA-1273-P301000021

Form: Safety Report Form

Data signed: (b) (4) 29 Apr 2021 15:47:47

Generated On: 10 Jun 2021 08:21:46

| | |
|--|--|
| SAEID | USA-US091-2021-MRNA-1273-P301000021 |
| Serious | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Death | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Life threatening | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Requires inpatient or prolongation of existing Hospitalization | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Persistent or significant disability or incapacity | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Congenital anomaly or birth defect | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Other medically important event | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Investigator's First Name | MILTON |
| Investigator's Last Name | HABER |
| Site Address: Street | 2344 LAGUNA DEL MAR, SUITE 201 |
| Site Address: City | LAREDO |
| Site Address: State | TX |
| Site Address: Postal Code | 78041 |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 1 |

US3572330

Folder: SAE USA-US091-2021-MRNA-1273-P301000021

Form: Safety Report Form (1)

Data signed: (b) (4) 29 Apr 2021 15:47:47

Generated On: 10 Jun 2021 08:21:46

| | |
|---|--|
| SAEID | USA-US091-2021-MRNA-1273-P301000021 |
| Serious | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Death | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Life threatening | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Requires inpatient or prolongation of existing Hospitalization | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Persistent or significant disability or incapacity | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Congenital anomaly or birth defect | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Other medically important event | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Investigator's First Name | MILTON |
| Investigator's Last Name | HABER |
| Site Address: Street | 2344 LAGUNA DEL MAR, SUITE 201 |
| Site Address: City | LAREDO |
| Site Address: State | TX |
| Site Address: Postal Code | 78041 |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 1 |
| Date of submission (Pre-filled from custom function) | 29/APR/2021 06:06 |
| Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge. | True |

Audit

US3572330 (Prod: Laguna Clinical Research Associates)

US3572330

Form: Participant Creation

Generated On: 10 Jun 2021 08:21:46

[Participant ID](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 11 Apr 2021 22:09:53 |
| User signature succeeded. | Milton Haber (b) (4) | 03 Apr 2021 05:07:34 |
| User entered 'US3572330' | (b) (4) RWS_ENDPOINT ENDPOINT (b) (4) | 21 Sep 2020 15:01:18 |

US3572330

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:21:46

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:00:53 |
| User signature succeeded. | Milton Haber (b) (4) | 22 Mar 2021 03:45:24 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 09 Dec 2020 21:46:15 |
| User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 21SEP2020 is reported under Visit 1 Day 1visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. '(Site from DM). | (b) (4), (b) (6) | 09 Dec 2020 04:46:24 |
| Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 21SEP2020 is reported under Visit 1 Day 1visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' answered with 'DATA UPDATED' (Site from DM). | (b) (4), (b) (6) | 08 Dec 2020 21:13:40 |
| User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 21SEP2020 is reported under Visit 1 Day 1visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. '(Site from DM). | (b) (4), (b) (6) | 22 Oct 2020 05:00:42 |
| User entered 'Yes (Y)' | Alisha Lutat (b) (4) | 21 Sep 2020 16:57:35 |
| | (b) (4) | |

US3572330

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:21:46

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

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:00:53 |
| User signature succeeded. | Milton Haber (b) (4) | 22 Mar 2021 03:45:24 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 09 Dec 2020 21:46:15 |
| User entered '21 SEP 2020' | RWS_ENDPOINT ENDPOINT (b) (4) | 21 Sep 2020 15:01:19 |

US3572330

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:21:46

[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 18:00:53 |
| User signature succeeded. | Milton Haber (b) (4) | 22 Mar 2021 03:45:24 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 09 Dec 2020 21:46:15 |
| Query 'Please complete all data entry for screening.' | (b) (4), (b) (6) | 09 Dec 2020 21:45:12 |
| canceled (Site from CRA). | | |
| User opened query 'Please complete all data entry for screening.' | (b) (4), (b) (6) | 12 Nov 2020 14:58:58 |
| (Site from CRA). | | |
| User entered 'Clinic (Clinic)' | Alisha Lutat (b) (4) | 21 Sep 2020 16:57:35 |
| | (b) (4) | |

US3572330

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:21:46

[Folder OID](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:00:53 |
| User entered 'SCRN' | System | 21 Sep 2020 16:57:35 |

US3572330

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:21:46

Date of Birth (MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:00:53 |
| User signature succeeded. | Milton Haber (b) (4) | 22 Mar 2021 03:45:24 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 09 Dec 2020 21:57:53 |
| User entered (b) (6) 1982' | RWS_ENDPOINT ENDPOINT (b) (4) | 21 Sep 2020 15:01:20 |

US3572330

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:21:46

[Age](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:00:53 |
| User signature succeeded. | Milton Haber (b) (4) | 22 Mar 2021 03:45:24 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 09 Dec 2020 21:57:53 |
| User entered '38' | Alisha Lutat (b) (4) (b) (4) | 21 Sep 2020 16:58:44 |

US3572330

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:21:46

[Age Units](#)

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:00:53 |
| User entered 'YEARS' | System | 21 Sep 2020 16:58:44 |

US3572330

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:21:46

[Age \(Derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:00:53 |
| User entered '38' | System | 21 Sep 2020 16:59:02 |

US3572330

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:21:46

[Sex](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:00:53 |
| User signature succeeded. | Milton Haber (b) (4) | 22 Mar 2021 03:45:24 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 09 Dec 2020 21:57:53 |
| User entered 'Male (M)' | Alisha Lutat (b) (4) (b) (4) | 21 Sep 2020 16:58:44 |

US3572330

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:21:46

[Ethnicity](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:00:53 |
| User signature succeeded. | Milton Haber (b) (4) | 22 Mar 2021 03:45:24 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 09 Dec 2020 21:57:53 |
| User entered 'Hispanic or Latino (HISPANIC OR LATINO)' | Alisha Lutat (b) (4) (b) (4) | 21 Sep 2020 16:58:44 |

US3572330

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:21:46

[White](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:00:53 |
| User signature succeeded. | Milton Haber (b) (4) | 22 Mar 2021 03:45:24 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 09 Dec 2020 21:57:53 |
| User entered 'l' | Alisha Lutat (b) (4) (b) (4) | 21 Sep 2020 16:58:44 |

US3572330

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:21:46

[Black](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:00:53 |
| User signature succeeded. | Milton Haber (b) (4) | 22 Mar 2021 03:45:24 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 09 Dec 2020 21:57:53 |
| User entered '0' | Alisha Lutat (b) (4) (b) (4) | 21 Sep 2020 16:58:44 |

US3572330

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:21:46

[Asian](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:00:53 |
| User signature succeeded. | Milton Haber (b) (4) | 22 Mar 2021 03:45:24 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 09 Dec 2020 21:57:53 |
| User entered '0' | Alisha Lutat (b) (4) (b) (4) | 21 Sep 2020 16:58:44 |

US3572330

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:21:46

[American Indian or Alaska Native](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:00:53 |
| User signature succeeded. | Milton Haber (b) (4) | 22 Mar 2021 03:45:24 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 09 Dec 2020 21:57:53 |
| User entered '0' | Alisha Lutat (b) (4) (b) (4) | 21 Sep 2020 16:58:44 |

US3572330

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:21:46

[Native Hawaiian or other Pacific Islander](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:00:53 |
| User signature succeeded. | Milton Haber (b) (4) | 22 Mar 2021 03:45:24 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 09 Dec 2020 21:57:53 |
| User entered '0' | Alisha Lutat (b) (4) (b) (4) | 21 Sep 2020 16:58:44 |

US3572330

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:21:46

[Other](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:00:53 |
| User signature succeeded. | Milton Haber (b) (4) | 22 Mar 2021 03:45:24 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 09 Dec 2020 21:57:53 |
| User entered '0' | Alisha Lutat (b) (4) (b) (4) | 21 Sep 2020 16:58:44 |

US3572330

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:21:46

[If race is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:00:53 |
| User signature succeeded. | Milton Haber (b) (4) | 22 Mar 2021 03:45:24 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 09 Dec 2020 21:57:53 |
| User entered empty. | Alisha Lutat (b) (4) (b) (4) | 21 Sep 2020 16:58:44 |

US3572330

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:21:46

[Unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:00:53 |
| User signature succeeded. | Milton Haber (b) (4) | 22 Mar 2021 03:45:24 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 09 Dec 2020 21:57:53 |
| User entered '0' | Alisha Lutat (b) (4) (b) (4) | 21 Sep 2020 16:58:44 |

US3572330

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:21:46

[Not reported](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:00:53 |
| User signature succeeded. | Milton Haber (b) (4) | 22 Mar 2021 03:45:24 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 09 Dec 2020 21:57:53 |
| User entered '0' | Alisha Lutat (b) (4) (b) (4) | 21 Sep 2020 16:58:44 |

US3572330

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:21:46

Date of Informed Consent (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:00:53 |
| User signature succeeded. | Milton Haber (b) (4) | 22 Mar 2021 03:45:24 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 09 Dec 2020 22:00:46 |
| User entered '21 Sep 2020' | Alisha Lutat (b) (4) (b) (4) | 21 Sep 2020 16:59:02 |

US3572330

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:21:46

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:00:53 |
| User entered 'Sep 2020' | System | 21 Sep 2020 16:59:02 |

US3572330

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:21:46

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:00:53 |
| User entered '2020' | System | 21 Sep 2020 16:59:02 |

US3572330

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:21:46

[Protocol Version](#)

| Audit | User | Time (GMT) |
|--------------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:00:53 |
| User signature succeeded. | Milton Haber (b) (4) | 22 Mar 2021 03:45:24 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 09 Dec 2020 22:00:46 |
| User entered 'Amendment 3 (3)' | Alisha Lutat (b) (4) (b) (4) | 21 Sep 2020 16:59:02 |

US3572330

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:21:46

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

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:00:53 |
| User signature succeeded. | Milton Haber (b) (4) | 22 Mar 2021 03:45:24 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 09 Dec 2020 22:00:46 |
| User entered 'Yes (Y)' | Alisha Lutat (b) (4) | 21 Sep 2020 16:59:02 |
| | (b) (4) | |

US3572330

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:21:46

[If No, indicate reason for screen fail](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:00:53 |
| User signature succeeded. | Milton Haber (b) (4) | 22 Mar 2021 03:45:24 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 09 Dec 2020 22:00:46 |
| User entered empty. | Alisha Lutat (b) (4) (b) (4) | 21 Sep 2020 16:59:02 |

US3572330

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:21:46

If reason for screen fail is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:00:53 |
| User signature succeeded. | Milton Haber (b) (4) | 22 Mar 2021 03:45:24 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 09 Dec 2020 22:00:46 |
| User entered empty. | Alisha Lutat (b) (4) (b) (4) | 21 Sep 2020 16:59:02 |

US3572330

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:21:46

[Was this participant screened previously?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:00:53 |
| User signature succeeded. | Milton Haber (b) (4) | 22 Mar 2021 03:45:24 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 09 Dec 2020 22:00:46 |
| User entered 'No (N)' | Alisha Lutat (b) (4) (b) (4) | 21 Sep 2020 16:59:02 |

US3572330

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:21:46

[If Yes, previous participant number](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:00:53 |
| User signature succeeded. | Milton Haber (b) (4) | 22 Mar 2021 03:45:24 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 09 Dec 2020 22:00:46 |
| User entered empty. | RWS_ENDPOINT | 21 Sep 2020 15:01:19 |
| | ENDPOINT (b) (4) | |
| | | |

US3572330

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:21:46

[Enrollment Trigger](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:00:53 |
| User entered 'l' | System | 21 Sep 2020 16:59:10 |

US3572330

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 08:21:46

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

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:00:53 |
| User signature succeeded. | Milton Haber (b) (4) | 22 Mar 2021 03:45:24 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 09 Dec 2020 22:01:04 |
| User entered 'Yes (Y)' | Alisha Lutat (b) (4) (b) (4) | 21 Sep 2020 16:59:10 |

US3572330

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 08:21:46

[Were any significant conditions reported?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:00:53 |
| User signature succeeded. | Milton Haber (b) (4) | 22 Mar 2021 03:45:24 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 09 Dec 2020 22:01:21 |
| User entered 'Yes (Y)' | Maria Candelario (b) (4) | 28 Oct 2020 01:50:08 |
| | (b) (4) | |

US3572330

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:21:46

[Condition](#)

| Audit | User | Time (GMT) |
|---|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:00:53 |
| User signature succeeded. | Milton Haber (b) (4) | 22 Mar 2021 03:45:24 |
| User closed query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' (Site from DM). | (b) (4) | 05 Feb 2021 09:13:50 |
| Query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' answered with 'Updated con med list in EDC per source information documented in medical history during screening' (Site from DM). | (b) (4), (b) (6) | 03 Feb 2021 17:48:58 |
| User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' (Site from DM). | (b) (4), (b) (6) | 14 Jan 2021 08:12:57 |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Dec 2020 22:01:33 |
| User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\23.0. | Coder Import (b) (4) | 28 Oct 2020 01:51:31 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0. | Coder Import (b) (4) | 28 Oct 2020 01:51:31 |
| Data point term sent to Coder | System | 28 Oct 2020 01:50:44 |
| User entered 'hypertension' | Maria Candelario (b) (4) | 28 Oct 2020 01:50:44 |

US3572330

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:21:46

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

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:00:53 |
| User signature succeeded. | Milton Haber (b) (4) | 22 Mar 2021 03:45:24 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 09 Dec 2020 22:01:33 |
| User entered '01 Jan 2019' | Maria Candelario (b) (4) | 28 Oct 2020 01:50:44 |
| | (b) (4) | |

US3572330

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:21:46

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:00:53 |
| User signature succeeded. | Milton Haber (b) (4) | 22 Mar 2021 03:45:24 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 09 Dec 2020 22:01:33 |
| User entered '0' | Maria Candelario (b) (4) | 28 Oct 2020 01:50:44 |
| | (b) (4) | |

US3572330

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:21:46

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:00:53 |
| User signature succeeded. | Milton Haber (b) (4) | 22 Mar 2021 03:45:24 |
| User closed query 'Per source, Losartan/HCTZ is noted on the CM log. Please review and reconcile the CM page in EDC.' (Site from CRA). | (b) (4) | |
| Query 'Per source, Losartan/HCTZ is noted on the CM log. Please review and reconcile the CM page in EDC.' answered with 'con med log in EDC reconciled and updated' (Site from CRA). | (b) (4), (b) (6) | 22 Feb 2021 10:13:19 |
| Query 'Per source, Losartan/HCTZ is noted on the CM log. Please review and reconcile the CM page in EDC.' answered with 'con med log in EDC reconciled and updated' (Site from CRA). | (b) (4), (b) (6) | 03 Feb 2021 17:49:27 |
| User opened query 'Per source, Losartan/HCTZ is noted on the CM log. Please review and reconcile the CM page in EDC.' (Site from CRA). | (b) (4), (b) (6) | 09 Dec 2020 22:03:32 |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Dec 2020 22:01:33 |
| User entered 'Yes (Y)' | Maria Candelario (b) (4) | 28 Oct 2020 01:50:44 |
| | (b) (4) | |

US3572330

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:21:46

[If No, please specify the stop date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:00:53 |
| User signature succeeded. | Milton Haber (b) (4) | 22 Mar 2021 03:45:24 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 09 Dec 2020 22:01:33 |
| User entered empty. | Maria Candelario (b) (4) | 28 Oct 2020 01:50:44 |
| | (b) (4) | |

US3572330

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:21:46

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:00:53 |
| User signature succeeded. | Milton Haber (b) (4) | 22 Mar 2021 03:45:24 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 09 Dec 2020 22:01:33 |
| User entered '0' | Maria Candelario (b) (4) (b) (4) | 28 Oct 2020 01:50:44 |

US3572330

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:21:46

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:00:53 |
| User entered 'Jan 2019' | System | 28 Oct 2020 01:50:44 |

US3572330

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:21:46

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:00:53 |
| User entered '2019' | System | 28 Oct 2020 01:50:44 |

US3572330

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:21:46

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:00:53 |
| User entered empty. | System | 28 Oct 2020 01:50:44 |

US3572330

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:21:46

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:00:53 |
| User entered empty. | System | 28 Oct 2020 01:50:44 |

US3572330

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:21:46

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:00:53 |
| User signature succeeded. | Milton Haber (b) (4) | 22 Mar 2021 03:45:24 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 09 Dec 2020 22:04:32 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 08 Dec 2020 21:12:26 |

US3572330

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:21:46

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:00:53 |
| User signature succeeded. | Milton Haber (b) (4) | 22 Mar 2021 03:45:24 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 09 Dec 2020 22:04:34 |
| User entered '21 Sep 2020' | (b) (4), (b) (6) | 08 Dec 2020 21:12:26 |

US3572330

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:21:46

[Time of assessment \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:00:53 |
| User signature succeeded. | Milton Haber (b) (4) | 22 Mar 2021 03:45:24 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 09 Dec 2020 22:04:36 |
| User entered '10:28' | (b) (4), (b) (6) | 08 Dec 2020 21:12:26 |

US3572330

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:21:46

[Vital Signs Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:00:53 |
| User entered '21 Sep 2020 10:28' | System | 08 Dec 2020 21:12:26 |

US3572330

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:21:46

[Height \(xxx.x\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:00:53 |
| User signature succeeded. | Milton Haber (b) (4) | 22 Mar 2021 03:45:24 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 09 Dec 2020 22:04:40 |
| User entered '70' in | (b) (4), (b) (6) | 08 Dec 2020 21:12:26 |
| DataPoint set to visible. | System | 21 Sep 2020 16:59:10 |

US3572330

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:21:46

[Weight \(xxx.x\)](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:00:53 |
| User signature succeeded. | Milton Haber (b) (4) | 22 Mar 2021 03:45:24 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 09 Dec 2020 22:04:41 |
| User entered '270' lb | (b) (4), (b) (6) | 08 Dec 2020 21:12:26 |
| DataPoint set to visible. | System | 21 Sep 2020 16:59:10 |

US3572330

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:21:46

[BMI \(xxx.x\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:00:53 |
| User entered '38.82197' | System | 08 Dec 2020 21:12:26 |
| DataPoint set to visible. | System | 21 Sep 2020 16:59:10 |

US3572330

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:21:46

[BMI units](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:00:53 |
| User entered 'kg/m2' | System | 08 Dec 2020 21:12:26 |
| DataPoint set to visible. | System | 21 Sep 2020 16:59:10 |

US3572330

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:21:46

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:00:53 |
| DataPoint Verified. | (b) (4), (b) (6) | 11 Apr 2021 22:10:41 |
| User signature succeeded. | Milton Haber (b) (4) | 22 Mar 2021 03:45:24 |
| User closed query 'Per source/guidelines, please capture temp and vitals under Day 1 and remove from screening page.' (Site from CRA). | (b) (4) | |
| Query 'Per source/guidelines, please capture temp and vitals under Day 1 and remove from screening page.' answered with 'updated' (Site from CRA). | (b) (4), (b) (6) | 22 Feb 2021 10:14:02 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4), (b) (6) | 05 Jan 2021 06:10:40 |
| User opened query 'Per source/guidelines, please capture temp and vitals under Day 1 and remove from screening page.' (Site from CRA). | (b) (4), (b) (6) | 05 Jan 2021 06:10:25 |
| User entered '97.7' F | (b) (4), (b) (6) | 09 Dec 2020 22:04:28 |
| | (b) (4), (b) (6) | 08 Dec 2020 21:12:26 |

US3572330

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:21:46

[Route of measurement](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:00:53 |
| DataPoint Verified. | (b) (4), (b) (6) | 11 Apr 2021 22:10:41 |
| User signature succeeded. | Milton Haber (b) (4) | 22 Mar 2021 03:45:24 |
| User entered empty; reason for change Data Entry Error | (b) (4) (u) (4), (b) (6) | 05 Jan 2021 06:10:25 |
| User entered 'Other (Other)' | (b) (4), (b) (6) | 08 Dec 2020 21:12:26 |

US3572330

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:21:46

[If Other, specify](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:00:53 |
| DataPoint Verified. | (b) (4), (b) (6) | 11 Apr 2021 22:10:41 |
| User signature succeeded. | Milton Haber (b) (4) | 22 Mar 2021 03:45:24 |
| User entered empty; reason for change Data Entry Error | (b) (4) (u) (4), (b) (6) | 05 Jan 2021 06:10:25 |
| User entered 'TEMPORAL' | (b) (4), (b) (6) | 08 Dec 2020 21:12:26 |

US3572330

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:21:46

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:00:53 |
| DataPoint Verified. | (b) (4), (b) (6) | 11 Apr 2021 22:10:41 |
| User signature succeeded. | Milton Haber (b) (4) | 22 Mar 2021 03:45:24 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4) (b) (4), (b) (6) | 05 Jan 2021 06:10:25 |
| User entered '90' | (b) (4), (b) (6) | 08 Dec 2020 21:12:26 |

US3572330

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:21:46

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:00:53 |
| User entered 'bpm' | System | 08 Dec 2020 21:12:26 |

US3572330

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:21:46

[Respiratory Rate \(xxx\)](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:00:53 |
| DataPoint Verified. | (b) (4), (b) (6) | 11 Apr 2021 22:10:41 |
| User signature succeeded. | Milton Haber (b) (4) | 22 Mar 2021 03:45:24 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4), (b) (6) | 05 Jan 2021 06:10:25 |
| User entered '18' | (b) (4), (b) (6) | 08 Dec 2020 21:12:26 |

US3572330

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:21:46

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:00:53 |
| User entered 'breaths/min' | System | 08 Dec 2020 21:12:26 |

US3572330

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:21:46

[Systolic Blood Pressure \(xxx\)](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:00:53 |
| DataPoint Verified. | (b) (4), (b) (6) | 11 Apr 2021 22:10:41 |
| User signature succeeded. | Milton Haber (b) (4) | 22 Mar 2021 03:45:24 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4) (b) (4), (b) (6) | 05 Jan 2021 06:10:25 |
| User entered '124' | (b) (4), (b) (6) | 08 Dec 2020 21:12:26 |

US3572330

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:21:46

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:00:53 |
| User entered 'mmHg' | System | 08 Dec 2020 21:12:26 |

US3572330

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:21:46

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:00:53 |
| DataPoint Verified. | (b) (4), (b) (6) | 11 Apr 2021 22:10:41 |
| User signature succeeded. | Milton Haber (b) (4) | 22 Mar 2021 03:45:24 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4), (b) (6) | 05 Jan 2021 06:10:25 |
| User entered '93' | (b) (4), (b) (6) | 08 Dec 2020 21:12:26 |

US3572330

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:21:46

Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:00:53 |
| User entered 'mmHg' | System | 08 Dec 2020 21:12:26 |

US3572330

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:21:46

[Height \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:00:53 |

US3572330

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:21:46

[Weight \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:00:53 |

US3572330

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 08:21:46

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:00:53 |
| User signature succeeded. | Milton Haber (b) (4) | 22 Mar 2021 03:45:24 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 09 Dec 2020 22:04:55 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 08 Dec 2020 21:12:40 |

US3572330

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 08:21:46

Date of examination (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:00:53 |
| User signature succeeded. | Milton Haber (b) (4) | 22 Mar 2021 03:45:24 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 09 Dec 2020 22:04:55 |
| User entered '21 Sep 2020' | (b) (4), (b) (6) | 08 Dec 2020 21:12:40 |

US3572330

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:21:46

[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 18:00:53 |
| User signature succeeded. | Milton Haber (b) (4) | 22 Mar 2021 03:45:24 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 09 Dec 2020 22:05:09 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 08 Dec 2020 21:13:14 |

US3572330

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:21:46

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 18:00:53 |
| User signature succeeded. | Milton Haber (b) (4) | 22 Mar 2021 03:45:24 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 09 Dec 2020 22:05:09 |
| User entered 'No (N)' | (b) (4), (b) (6) | 08 Dec 2020 21:13:14 |

US3572330

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:21:46

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 18:00:53 |
| User signature succeeded. | Milton Haber (b) (4) | 22 Mar 2021 03:45:24 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 09 Dec 2020 22:05:09 |
| User entered 'No (N)' | (b) (4), (b) (6) | 08 Dec 2020 21:13:14 |

US3572330

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:21:46

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 18:00:53 |
| User signature succeeded. | Milton Haber (b) (4) | 22 Mar 2021 03:45:24 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 09 Dec 2020 22:05:09 |
| User entered 'No (N)' | (b) (4), (b) (6) | 08 Dec 2020 21:13:14 |

US3572330

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:21:46

[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 18:00:53 |
| User signature succeeded. | Milton Haber (b) (4) | 22 Mar 2021 03:45:24 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 09 Dec 2020 22:05:09 |
| User entered 'No (N)' | (b) (4), (b) (6) | 08 Dec 2020 21:13:14 |

US3572330

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:21:46

[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 18:00:53 |
| User signature succeeded. | Milton Haber (b) (4) | 22 Mar 2021 03:45:24 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 09 Dec 2020 22:05:09 |
| User entered 'No (N)' | (b) (4), (b) (6) | 08 Dec 2020 21:13:14 |

US3572330

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:21:46

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 18:00:53 |
| User signature succeeded. | Milton Haber (b) (4) | 22 Mar 2021 03:45:24 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 09 Dec 2020 22:05:09 |
| User entered 'No (N)' | (b) (4), (b) (6) | 08 Dec 2020 21:13:14 |

US3572330

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:21:46

[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 18:00:53 |
| User signature succeeded. | Milton Haber (b) (4) | 22 Mar 2021 03:45:24 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 09 Dec 2020 22:05:09 |
| User entered 'No (N)' | (b) (4), (b) (6) | 08 Dec 2020 21:13:14 |

US3572330

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:21:46

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 18:00:53 |
| User signature succeeded. | Milton Haber (b) (4) | 22 Mar 2021 03:45:24 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 09 Dec 2020 22:05:09 |
| User entered 'No (N)' | (b) (4), (b) (6) | 08 Dec 2020 21:13:14 |

US3572330

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:21:46

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 18:00:53 |
| User signature succeeded. | Milton Haber (b) (4) | 22 Mar 2021 03:45:24 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 09 Dec 2020 22:05:09 |
| User entered 'No (N)' | (b) (4), (b) (6) | 08 Dec 2020 21:13:14 |

US3572330

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:21:46

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 18:00:53 |
| User signature succeeded. | Milton Haber (b) (4) | 22 Mar 2021 03:45:24 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 09 Dec 2020 22:05:09 |
| User entered 'No (N)' | (b) (4), (b) (6) | 08 Dec 2020 21:13:14 |

US3572330

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:21:46

Other

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:00:53 |
| User signature succeeded. | Milton Haber (b) (4) | 22 Mar 2021 03:45:24 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 09 Dec 2020 22:05:09 |
| User entered 'No (N)' | (b) (4), (b) (6) | 08 Dec 2020 21:13:14 |

US3572330

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:21:46

[Specify](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:00:53 |
| User signature succeeded. | Milton Haber (b) (4) | 22 Mar 2021 03:45:24 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 09 Dec 2020 22:05:09 |
| User entered empty. | (b) (4), (b) (6) | 08 Dec 2020 21:13:14 |

US3572330

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:21:46

No Risk Identified

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:00:53 |
| User signature succeeded. | Milton Haber (b) (4) | 22 Mar 2021 03:45:24 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 08 Dec 2020 21:13:14 |

US3572330

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:21:46

[Resides in Nursing Home or Assisted Living Facility](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:00:53 |
| User signature succeeded. | Milton Haber (b) (4) | 22 Mar 2021 03:45:24 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 09 Dec 2020 22:05:09 |
| User entered '0' | (b) (4), (b) (6) | 08 Dec 2020 21:13:14 |

US3572330

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:21:46

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 18:00:53 |
| User signature succeeded. | Milton Haber (b) (4) | 22 Mar 2021 03:45:24 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 09 Dec 2020 22:05:09 |
| User entered '0' | (b) (4), (b) (6) | 08 Dec 2020 21:13:14 |

US3572330

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:21:46

[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 18:00:53 |
| User signature succeeded. | Milton Haber (b) (4) | 22 Mar 2021 03:45:24 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 09 Dec 2020 22:05:09 |
| User entered '0' | (b) (4), (b) (6) | 08 Dec 2020 21:13:14 |

US3572330

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:21:46

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 18:00:53 |
| User signature succeeded. | Milton Haber (b) (4) | 22 Mar 2021 03:45:24 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 09 Dec 2020 22:05:09 |
| User entered '0' | (b) (4), (b) (6) | 08 Dec 2020 21:13:14 |

US3572330

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:21:46

[Resides in a single family home \(i.e., detached housing\)](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:00:53 |
| User signature succeeded. | Milton Haber (b) (4) | 22 Mar 2021 03:45:24 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 09 Dec 2020 22:05:09 |
| User entered 'l' | (b) (4), (b) (6) | 08 Dec 2020 21:13:14 |

US3572330

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:21:46

[Other](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:00:53 |
| User signature succeeded. | Milton Haber (b) (4) | 22 Mar 2021 03:45:24 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 08 Dec 2020 21:13:14 |

US3572330

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:21:46

[Specify](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:00:53 |
| User signature succeeded. | Milton Haber (b) (4) | 22 Mar 2021 03:45:24 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 09 Dec 2020 22:05:09 |
| User entered empty. | (b) (4), (b) (6) | 08 Dec 2020 21:13:14 |

US3572330

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:21:46

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User signature succeeded. | Milton Haber (b) (4) | 21 Mar 2021 00:25:10 |
| DataPoint Verified. | (b) (4) (u) (4), (b) (6) | 09 Dec 2020 22:05:16 |
| User entered 'Yes (Y)' | Maria Candelario (b) (4) (b) (4) | 28 Oct 2020 01:52:44 |

US3572330

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:21:46

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

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User signature succeeded. | Milton Haber (b) (4) | 21 Mar 2021 00:25:10 |
| DataPoint Verified. | (b) (4) (u) (4), (b) (6) | 09 Dec 2020 22:05:16 |
| User entered '21 Sep 2020' | Maria Candelario (b) (4) (b) (4) | 28 Oct 2020 01:52:44 |

US3572330

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:21:46

[Was visit performed at the participant's home or at the clinic?](#)

| Audit | User | Time (GMT) |
|--------------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User signature succeeded. | Milton Haber (b) (4) | 21 Mar 2021 00:25:10 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 09 Dec 2020 22:05:16 |
| User entered 'Clinic (Clinic)' | Maria Candelario (b) (4) (b) (4) | 28 Oct 2020 01:52:44 |

US3572330

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:21:46

[Folder OID](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User entered 'VISIT1' | System | 28 Oct 2020 01:52:44 |

US3572330

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:21:46

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

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User signature succeeded. | Milton Haber (b) (4) | 21 Mar 2021 00:25:10 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 09 Dec 2020 22:05:36 |
| User entered '21 SEP 2020' | RWS_ENDPOINT ENDPOINT (b) (4) | 21 Sep 2020 15:32:07 |

US3572330

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:21:46

[What was the participant's randomization number?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User signature succeeded. | Milton Haber (b) (4) | 21 Mar 2021 00:25:10 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 09 Dec 2020 22:05:36 |
| User entered '114434' | RWS_ENDPOINT ENDPOINT (b) (4) | 21 Sep 2020 15:32:07 |

US3572330

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:21:46

[In what Cohort was the participant enrolled?](#)

| Audit | User | Time (GMT) |
|---|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User signature succeeded. | Milton Haber (b) (4) | 21 Mar 2021 00:25:10 |
| DataPoint Verified. | (b) (4) (u) (4), (b) (6) | 09 Dec 2020 22:05:36 |
| User entered '>=18 and <65 years and not at risk (1)' | RWS_ENDPOINT ENDPOINT (b) (4) | 21 Sep 2020 15:32:07 |

US3572330

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:21:46

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) | 24 Apr 2021 14:40:44 |
| User signature succeeded. | Milton Haber (b) (4) | 21 Mar 2021 00:25:10 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 09 Dec 2020 22:05:36 |
| User entered 'No (N)' | Maria Candelario (b) (4) (b) (4) | 28 Oct 2020 01:55:31 |

US3572330

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:21:46

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) | 24 Apr 2021 14:40:44 |
| User signature succeeded. | Milton Haber (b) (4) | 21 Mar 2021 00:25:10 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 09 Dec 2020 22:05:36 |
| User entered 'No (N)' | Maria Candelario (b) (4) (b) (4) | 28 Oct 2020 01:55:31 |

US3572330

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:21:46

Severe obesity (body mass index > or = 40kg/m2

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User signature succeeded. | Milton Haber (b) (4) | 21 Mar 2021 00:25:10 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 09 Dec 2020 22:05:36 |
| User entered 'No (N)' | Maria Candelario (b) (4) (b) (4) | 28 Oct 2020 01:55:31 |

US3572330

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:21:46

Diabetes (Type I, Type 2, or gestational)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User signature succeeded. | Milton Haber (b) (4) | 21 Mar 2021 00:25:10 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 09 Dec 2020 22:05:36 |
| User entered 'No (N)' | Maria Candelario (b) (4) (b) (4) | 28 Oct 2020 01:55:31 |

US3572330

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:21:46

[Liver Disease](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User signature succeeded. | Milton Haber (b) (4) | 21 Mar 2021 00:25:10 |
| DataPoint Verified. | (b) (4) (u) (4), (b) (6) | 09 Dec 2020 22:05:36 |
| User entered 'No (N)' | Maria Candelario (b) (4) (b) (4) | 28 Oct 2020 01:55:31 |

US3572330

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:21:46

[Human Immunodeficiency Virus \(HIV\) infection](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User signature succeeded. | Milton Haber (b) (4) | 21 Mar 2021 00:25:10 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 09 Dec 2020 22:05:36 |
| User entered 'No (N)' | Maria Candelario (b) (4) | 28 Oct 2020 01:55:31 |
| DataPoint set to visible. | (b) (4) System | 21 Sep 2020 16:59:02 |

US3572330

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:21:46

Height

| Audit | User | Time (GMT) |
|---|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 11 Apr 2021 22:11:34 |
| User signature succeeded. | Milton Haber (b) (4) | 21 Mar 2021 00:25:10 |
| User closed query 'Per CDM RQ: Patient noted as screened and dosed same day. Per CCG, "ND" should be recorded at height and weight. Please update accordingly.' (Site from DM). | (b) (4), (b) (6) | 07 Jan 2021 06:33:25 |
| Query 'Per CDM RQ: Patient noted as screened and dosed same day. Per CCG, "ND" should be recorded at height and weight. Please update accordingly.' answered with 'updated' (Site from DM). | (b) (4), (b) (6) | 06 Jan 2021 02:05:03 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4), (b) (6) | 06 Jan 2021 02:04:55 |
| User opened query 'Per CDM RQ: Patient noted as screened and dosed same day. Per CCG, "ND" should be recorded at height and weight. Please update accordingly.' (Site from DM). | (b) (4), (b) (6) | 10 Dec 2020 06:20:41 |
| User closed query 'Per CDM: Patient noted as screened and dosed same day. Per CCG, "ND" should be recorded at height and weight. Please update accordingly.' (Site from DM). | (b) (4), (b) (6) | 10 Dec 2020 06:20:41 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 09 Dec 2020 22:06:48 |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Dec 2020 22:06:45 |
| Query 'Per CDM: Patient noted as screened and dosed same day. Per CCG, "ND" should be recorded at height and weight. Please update accordingly.' answered with 'DATA UPDATED' (Site from DM). | (b) (4), (b) (6) | 08 Dec 2020 21:14:43 |
| User opened query 'Per CDM: Patient noted as screened and dosed same day. Per CCG, "ND" should be recorded at height and weight. Please update accordingly.' (Site from DM). | (b) (4), (b) (6) | 10 Nov 2020 09:42:32 |
| User entered '70' in | Maria Candelario (b) (4) (b) (4) | 28 Oct 2020 01:55:13 |

US3572330

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:21:46

[Weight](#)

| Audit | User | Time (GMT) |
|---|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 11 Apr 2021 22:11:34 |
| User signature succeeded. | Milton Haber (b) (4) | 21 Mar 2021 00:25:10 |
| User entered missing code ND - Not Done; reason for | (b) (4) | |
| change Data Entry Error | (b) (4), (b) (6) | 06 Jan 2021 02:04:55 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 09 Dec 2020 22:06:46 |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Dec 2020 22:06:45 |
| User entered '270' lb | Maria Candelario (b) (4) | 28 Oct 2020 01:55:13 |
| | (b) (4) | |

US3572330

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:21:46

Height

| Audit | User | Time (GMT) |
|---|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 11 Apr 2021 22:11:34 |
| User signature succeeded. | Milton Haber (b) (4) | 21 Mar 2021 00:25:10 |
| User closed query 'Per CDM RQ: Patient noted as screened and dosed same day. Per CCG, "ND" should be recorded at height and weight. Please update accordingly.' (Site from DM). | (b) (4), (b) (6) | 07 Jan 2021 06:33:25 |
| Query 'Per CDM RQ: Patient noted as screened and dosed same day. Per CCG, "ND" should be recorded at height and weight. Please update accordingly.' answered with 'updated' (Site from DM). | (b) (4), (b) (6) | 06 Jan 2021 02:05:03 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4), (b) (6) | 06 Jan 2021 02:04:55 |
| User opened query 'Per CDM RQ: Patient noted as screened and dosed same day. Per CCG, "ND" should be recorded at height and weight. Please update accordingly.' (Site from DM). | (b) (4), (b) (6) | 10 Dec 2020 06:20:41 |
| User closed query 'Per CDM: Patient noted as screened and dosed same day. Per CCG, "ND" should be recorded at height and weight. Please update accordingly.' (Site from DM). | (b) (4), (b) (6) | 10 Dec 2020 06:20:41 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 09 Dec 2020 22:06:48 |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Dec 2020 22:06:45 |
| Query 'Per CDM: Patient noted as screened and dosed same day. Per CCG, "ND" should be recorded at height and weight. Please update accordingly.' answered with 'DATA UPDATED' (Site from DM). | (b) (4), (b) (6) | 08 Dec 2020 21:14:43 |
| User opened query 'Per CDM: Patient noted as screened and dosed same day. Per CCG, "ND" should be recorded at height and weight. Please update accordingly.' (Site from DM). | (b) (4), (b) (6) | 10 Nov 2020 09:42:32 |
| User entered '70' in | Maria Candelario (b) (4) (b) (4) | 28 Oct 2020 01:55:13 |

US3572330

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:21:46

[Weight](#)

| Audit | User | Time (GMT) |
|--|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 11 Apr 2021 22:11:34 |
| User signature succeeded. | Milton Haber (b) (4) | 21 Mar 2021 00:25:10 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4), (b) (6) | 06 Jan 2021 02:04:55 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 09 Dec 2020 22:06:46 |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Dec 2020 22:06:45 |
| User entered '270' lb | Maria Candelario (b) (4) (b) (4) | 28 Oct 2020 01:55:13 |

US3572330

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:21:46

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User accepted default value 'Pre-Dose (PREDOSE)' | Maria Candelario (b) (4) (b) (4) | 28 Oct 2020 01:55:13 |

US3572330

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:21:46

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User signature succeeded. | Milton Haber (b) (4) | 21 Mar 2021 00:25:10 |
| DataPoint Verified. | (b) (4) (u) (4), (b) (6) | 09 Dec 2020 22:06:45 |
| User entered 'Yes (Y)' | Maria Candelario (b) (4) (b) (4) | 28 Oct 2020 01:55:13 |

US3572330

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:21:46

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User signature succeeded. | Milton Haber (b) (4) | 21 Mar 2021 00:25:10 |
| DataPoint Verified. | (b) (4) (u) (4), (b) (6) | 09 Dec 2020 22:06:45 |
| User entered '21 Sep 2020' | Maria Candelario (b) (4) (b) (4) | 28 Oct 2020 01:55:13 |

US3572330

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:21:46

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

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 11 Apr 2021 22:11:34 |
| User signature succeeded. | Milton Haber (b) (4) | 21 Mar 2021 00:25:10 |
| User closed query 'Per source, 1033 is noted. Please review and reconcile.' (Site from CRA). | (b) (4) | |
| Query 'Per source, 1033 is noted. Please review and reconcile.' answered with 'updated' (Site from CRA). | (b) (4), (b) (6) | 22 Feb 2021 10:14:17 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 06 Jan 2021 02:05:29 |
| User entered '10:33' reason for change: Data Entry Error | (b) (4), (b) (6) | 06 Jan 2021 02:05:22 |
| DataPoint Verified. | (b) (4), (b) (6) | 06 Jan 2021 02:05:22 |
| User entered '10:33' reason for change: Data Entry Error | (b) (4), (b) (6) | 09 Dec 2020 22:06:45 |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Dec 2020 22:06:11 |
| User opened query 'Per source, 1033 is noted. Please review and reconcile.' (Site from CRA). | (b) (4), (b) (6) | 09 Dec 2020 22:06:11 |
| User entered '10:28' | Maria Candelario (b) (4) | 28 Oct 2020 01:55:13 |
| | (b) (4) | |

US3572330

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:21:46

[Vital Signs Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User entered '21 Sep 2020 10:33' | System | 06 Jan 2021 02:05:22 |
| User entered '21 Sep 2020 10:28' | System | 28 Oct 2020 01:55:13 |

US3572330

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:21:46

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User signature succeeded. | Milton Haber (b) (4) | 21 Mar 2021 00:25:10 |
| DataPoint Verified. | (b) (4) (u) (4), (b) (6) | 09 Dec 2020 22:06:45 |
| User entered '97.7' F | Maria Candelario (b) (4) (b) (4) | 28 Oct 2020 01:55:13 |

US3572330

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:21:46

[Route of measurement](#)

| Audit | User | Time (GMT) |
|------------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User signature succeeded. | Milton Haber (b) (4) | 21 Mar 2021 00:25:10 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 09 Dec 2020 22:06:45 |
| User entered 'Other (Other)' | Maria Candelario (b) (4) (b) (4) | 28 Oct 2020 01:55:13 |

US3572330

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:21:46

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User signature succeeded. | Milton Haber (b) (4) | 21 Mar 2021 00:25:10 |
| DataPoint Verified. | (b) (4) (u) (4), (b) (6) | 09 Dec 2020 22:06:45 |
| User entered 'temporal' | Maria Candelario (b) (4) (b) (4) | 28 Oct 2020 01:55:13 |

US3572330

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:21:46

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User signature succeeded. | Milton Haber (b) (4) | 21 Mar 2021 00:25:10 |
| DataPoint Verified. | (b) (4) (u) (4), (b) (6) | 09 Dec 2020 22:06:45 |
| User entered '90' | Maria Candelario (b) (4) (b) (4) | 28 Oct 2020 01:55:13 |

US3572330

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:21:46

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User entered 'bpm' | System | 28 Oct 2020 01:55:13 |

US3572330

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:21:46

[Respiratory Rate \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User signature succeeded. | Milton Haber (b) (4) | 21 Mar 2021 00:25:10 |
| DataPoint Verified. | (b) (4) (u) (4), (b) (6) | 09 Dec 2020 22:06:45 |
| User entered '18' | Maria Candelario (b) (4) (b) (4) | 28 Oct 2020 01:55:13 |

US3572330

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:21:46

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User entered 'breaths/min' | System | 28 Oct 2020 01:55:13 |

US3572330

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:21:46

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User signature succeeded. | Milton Haber (b) (4) | 21 Mar 2021 00:25:10 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 09 Dec 2020 22:06:45 |
| User entered '124' | Maria Candelario (b) (4) (b) (4) | 28 Oct 2020 01:55:13 |

US3572330

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:21:46

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User entered 'mmHg' | System | 28 Oct 2020 01:55:13 |

US3572330

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:21:46

[Diastolic Blood Pressure \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User signature succeeded. | Milton Haber (b) (4) | 21 Mar 2021 00:25:10 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 09 Dec 2020 22:06:45 |
| User entered '93' | Maria Candelario (b) (4) (b) (4) | 28 Oct 2020 01:55:13 |

US3572330

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:21:46

Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User entered 'mmHg' | System | 28 Oct 2020 01:55:13 |

US3572330

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:21:46

Height

| Audit | User | Time (GMT) |
|---|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 11 Apr 2021 22:11:34 |
| User signature succeeded. | Milton Haber (b) (4) | 21 Mar 2021 00:25:10 |
| User closed query 'Per CDM RQ: Patient noted as screened and dosed same day. Per CCG, "ND" should be recorded at height and weight. Please update accordingly.' (Site from DM). | (b) (4), (b) (6) | 07 Jan 2021 06:33:25 |
| Query 'Per CDM RQ: Patient noted as screened and dosed same day. Per CCG, "ND" should be recorded at height and weight. Please update accordingly.' answered with 'updated' (Site from DM). | (b) (4), (b) (6) | 06 Jan 2021 02:05:03 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4), (b) (6) | 06 Jan 2021 02:04:55 |
| User opened query 'Per CDM RQ: Patient noted as screened and dosed same day. Per CCG, "ND" should be recorded at height and weight. Please update accordingly.' (Site from DM). | (b) (4), (b) (6) | 10 Dec 2020 06:20:41 |
| User closed query 'Per CDM: Patient noted as screened and dosed same day. Per CCG, "ND" should be recorded at height and weight. Please update accordingly.' (Site from DM). | (b) (4), (b) (6) | 10 Dec 2020 06:20:41 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 09 Dec 2020 22:06:48 |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Dec 2020 22:06:45 |
| Query 'Per CDM: Patient noted as screened and dosed same day. Per CCG, "ND" should be recorded at height and weight. Please update accordingly.' answered with 'DATA UPDATED' (Site from DM). | (b) (4), (b) (6) | 08 Dec 2020 21:14:43 |
| User opened query 'Per CDM: Patient noted as screened and dosed same day. Per CCG, "ND" should be recorded at height and weight. Please update accordingly.' (Site from DM). | (b) (4), (b) (6) | 10 Nov 2020 09:42:32 |
| User entered '70' in | Maria Candelario (b) (4) (b) (4) | 28 Oct 2020 01:55:13 |

US3572330

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:21:46

[Weight](#)

| Audit | User | Time (GMT) |
|--|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 11 Apr 2021 22:11:34 |
| User signature succeeded. | Milton Haber (b) (4) | 21 Mar 2021 00:25:10 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4), (b) (6) | 06 Jan 2021 02:04:55 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 09 Dec 2020 22:06:46 |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Dec 2020 22:06:45 |
| User entered '270' lb | Maria Candelario (b) (4) (b) (4) | 28 Oct 2020 01:55:13 |

US3572330

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:21:46

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User accepted default value 'Post-Dose (POSTDOSE)' | Maria Candelario (b) (4) (b) (4) | 28 Oct 2020 01:55:13 |

US3572330

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:21:46

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User signature succeeded. | Milton Haber (b) (4) | 21 Mar 2021 00:25:10 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 09 Dec 2020 22:06:45 |
| User entered 'Yes (Y)' | Maria Candelario (b) (4) (b) (4) | 28 Oct 2020 01:55:13 |

US3572330

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:21:46

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User signature succeeded. | Milton Haber (b) (4) | 21 Mar 2021 00:25:10 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 09 Dec 2020 22:06:45 |
| User entered '21 Sep 2020' | Maria Candelario (b) (4) (b) (4) | 28 Oct 2020 01:55:13 |

US3572330

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:21:46

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

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User signature succeeded. | Milton Haber (b) (4) | 21 Mar 2021 00:25:10 |
| DataPoint Verified. | (b) (4) (u) (4), (b) (6) | 09 Dec 2020 22:06:45 |
| User entered '11:52' | Maria Candelario (b) (4) (b) (4) | 28 Oct 2020 01:55:13 |

US3572330

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:21:46

[Vital Signs Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User entered '21 Sep 2020 11:52' | System | 28 Oct 2020 01:55:13 |

US3572330

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:21:46

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User signature succeeded. | Milton Haber (b) (4) | 21 Mar 2021 00:25:10 |
| DataPoint Verified. | (b) (4) (u) (4), (b) (6) | 09 Dec 2020 22:06:45 |
| User entered '97.8' F | Maria Candelario (b) (4) (b) (4) | 28 Oct 2020 01:55:13 |

US3572330

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:21:46

[Route of measurement](#)

| Audit | User | Time (GMT) |
|------------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User signature succeeded. | Milton Haber (b) (4) | 21 Mar 2021 00:25:10 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 09 Dec 2020 22:06:45 |
| User entered 'Other (Other)' | Maria Candelario (b) (4) (b) (4) | 28 Oct 2020 01:55:13 |

US3572330

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:21:46

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User signature succeeded. | Milton Haber (b) (4) | 21 Mar 2021 00:25:10 |
| DataPoint Verified. | (b) (4) (u) (4), (b) (6) | 09 Dec 2020 22:06:45 |
| User entered 'temporal' | Maria Candelario (b) (4) (b) (4) | 28 Oct 2020 01:55:13 |

US3572330

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:21:46

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User signature succeeded. | Milton Haber (b) (4) | 21 Mar 2021 00:25:10 |
| DataPoint Verified. | (b) (4) (u) (4), (b) (6) | 09 Dec 2020 22:06:45 |
| User entered '62' | Maria Candelario (b) (4) (b) (4) | 28 Oct 2020 01:55:13 |

US3572330

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:21:46

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User entered 'bpm' | System | 28 Oct 2020 01:55:13 |

US3572330

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:21:46

[Respiratory Rate \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User signature succeeded. | Milton Haber (b) (4) | 21 Mar 2021 00:25:10 |
| DataPoint Verified. | (b) (4) (u) (4), (b) (6) | 09 Dec 2020 22:06:45 |
| User entered '18' | Maria Candelario (b) (4) (b) (4) | 28 Oct 2020 01:55:13 |

US3572330

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:21:46

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User entered 'breaths/min' | System | 28 Oct 2020 01:55:13 |

US3572330

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:21:46

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User signature succeeded. | Milton Haber (b) (4) | 21 Mar 2021 00:25:10 |
| DataPoint Verified. | (b) (4) (u) (4), (b) (6) | 09 Dec 2020 22:06:45 |
| User entered '136' | Maria Candelario (b) (4) (b) (4) | 28 Oct 2020 01:55:13 |

US3572330

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:21:46

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User entered 'mmHg' | System | 28 Oct 2020 01:55:13 |

US3572330

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:21:46

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User signature succeeded. | Milton Haber (b) (4) | 21 Mar 2021 00:25:10 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 09 Dec 2020 22:06:45 |
| User entered '86' | Maria Candelario (b) (4) (b) (4) | 28 Oct 2020 01:55:13 |

US3572330

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:21:46

Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User entered 'mmHg' | System | 28 Oct 2020 01:55:13 |

US3572330

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 08:21:46

Was the physical examination performed?

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 17:23:08 |
| User signature succeeded. | Milton Haber (b) (4) | 21 Mar 2021 00:25:10 |
| User closed query 'Patient noted as screened and dosed same day. Per CCG, "No" should be recorded at PE. Please update accordingly' (Site from CRA). | (b) (4) | 28 Feb 2021 19:36:47 |
| Query 'Patient noted as screened and dosed same day. Per CCG, "No" should be recorded at PE. Please update accordingly' answered with 'updated' (Site from CRA). | (b) (4), (b) (6) | 04 Jan 2021 07:56:42 |
| User entered 'No (N)' reason for change: Data Entry Error | (b) (4), (b) (6) | 04 Jan 2021 07:56:34 |
| User opened query 'Patient noted as screened and dosed same day. Per CCG, "No" should be recorded at PE. Please update accordingly' (Site from CRA). | (b) (4), (b) (6) | 09 Dec 2020 22:07:39 |
| User entered 'Yes (Y)' | Maria Candelario (b) (4) | 28 Oct 2020 01:51:22 |
| | (b) (4) | |

US3572330

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 08:21:46

Date of examination (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 17:23:08 |
| User signature succeeded. | Milton Haber (b) (4) | 21 Mar 2021 00:25:10 |
| User entered empty; reason for change Data Entry Error | (b) (4) (u) (4), (b) (6) | 04 Jan 2021 07:56:34 |
| User entered '21 Sep 2020' | Maria Candelario (b) (4) (b) (4) | 28 Oct 2020 01:51:22 |

US3572330

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:21:46

[Was study treatment given?](#)

| Audit | User | Time (GMT) |
|---|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User signature succeeded. | Milton Haber (b) (4) | 21 Mar 2021 00:25:10 |
| User closed query 'Per CDM: Study treatment was given to the patient and "VISIT DATE" form is blank please review and update accordingly.' (Site from DM). | (b) (4), (b) (6) | 10 Dec 2020 06:15:51 |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Dec 2020 22:08:24 |
| User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 21SEP2020 is reported under Visit 1 Day 1 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM). | (b) (4), (b) (6) | 09 Dec 2020 07:09:52 |
| Query 'Per CDM: Study treatment was given to the patient and "VISIT DATE" form is blank, please review and update accordingly.' answered with 'DATA UPDATED' (Site from DM). | (b) (4), (b) (6) | 08 Dec 2020 21:15:09 |
| Query 'Per GCL Lab Reconciliation: Swab: Sample dated 21SEP2020 is reported under Visit 1 Day 1 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' answered with 'DATA UPDATED' (Site from DM). | (b) (4), (b) (6) | 08 Dec 2020 21:15:04 |
| Query 'Per GCL Lab Recon: GCL has Immunogenicity Assessment for Visit 1 Day 1 dated 21SEP2020 however the same is missing in EDC. Please add or clarify' canceled (Site from DM). | (b) (4), (b) (6) | 17 Nov 2020 14:02:05 |
| User opened query 'Per CDM: Study treatment was given to the patient and "VISIT DATE" form is blank please review and update accordingly.' (Site from DM). | (b) (4), (b) (6) | 04 Nov 2020 13:55:38 |
| User opened query 'Per GCL Lab Recon: GCL has Immunogenicity Assessment for Visit 1 Day 1 dated 21SEP2020 however the same is missing in EDC. Please add or clarify' (Site from DM). | Stacie Zwiesler (b) (4) | 24 Oct 2020 15:16:49 |

US3572330

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:21:46

[Was study treatment given?](#)

| Audit | User | Time (GMT) |
|---|---------------------------------|----------------------|
| User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 21SEP2020 is reported under Visit 1 Day 1 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM). | (b) (4), (b) (6) | 22 Oct 2020 09:10:24 |
| User entered 'Yes (Y)' | Alisha Lutat (b) (4) (b) (4) | 21 Sep 2020 16:59:44 |

US3572330

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:21:46

[If No, reason not given](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User signature succeeded. | Milton Haber (b) (4) | 21 Mar 2021 00:25:10 |
| DataPoint Verified. | (b) (4) (u) (4), (b) (6) | 09 Dec 2020 22:08:24 |
| User entered empty. | Alisha Lutat (b) (4) (b) (4) | 21 Sep 2020 16:59:44 |

US3572330

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:21:46

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) | 24 Apr 2021 14:40:44 |
| User signature succeeded. | Milton Haber (b) (4) | 21 Mar 2021 00:25:10 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 09 Dec 2020 22:08:24 |
| User entered empty. | Alisha Lutat (b) (4) (b) (4) | 21 Sep 2020 16:59:44 |

US3572330

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:21:46

[What was the study treatment?](#)

| Audit | User | Time (GMT) |
|-------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User entered 'MRNA-1273 OR PLACEBO' | System | 21 Sep 2020 16:59:44 |

US3572330

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:21:46

What was the treatment date? (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User signature succeeded. | Milton Haber (b) (4) | 21 Mar 2021 00:25:10 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 09 Dec 2020 22:08:24 |
| User entered '21 Sep 2020' | Alisha Lutat (b) (4) (b) (4) | 21 Sep 2020 16:59:44 |

US3572330

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:21:46

[What was the treatment time? \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User signature succeeded. | Milton Haber (b) (4) | 21 Mar 2021 00:25:10 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 09 Dec 2020 22:08:24 |
| User entered '11:22' | Alisha Lutat (b) (4) (b) (4) | 21 Sep 2020 16:59:44 |

US3572330

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:21:46

[Treatment Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User entered '21 Sep 2020 11:22' | System | 21 Sep 2020 16:59:44 |

US3572330

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:21:46

[Which arm was used to give treatment?](#)

| Audit | User | Time (GMT) |
|------------------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User signature succeeded. | Milton Haber (b) (4) | 21 Mar 2021 00:25:10 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 09 Dec 2020 22:08:24 |
| User entered 'Left Arm (LEFT ARM)' | Alisha Lutat (b) (4) (b) (4) | 21 Sep 2020 16:59:44 |

US3572330

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:21:46

[What was the frequency of the study treatment dosing?](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Dec 2020 22:08:24 |
| User entered 'ONCE' | System | 21 Sep 2020 16:59:44 |

US3572330

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:21:46

What was the route of administration for the study treatment?

| Audit | User | Time (GMT) |
|------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User entered 'INTRAMUSCULAR' | System | 21 Sep 2020 16:59:44 |

US3572330

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:21:46

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User signature succeeded. | Milton Haber (b) (4) | 21 Mar 2021 00:25:10 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 09 Dec 2020 22:08:47 |
| User entered 'Yes (Y)' | Maria Candelario (b) (4) (b) (4) | 28 Oct 2020 01:52:09 |

US3572330

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:21:46

Collection date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 11 Apr 2021 22:12:08 |
| User signature succeeded. | Milton Haber (b) (4) | 21 Mar 2021 00:25:10 |
| User closed query 'Previous query response indicates, "updtad", however, nothing was changed in EDC. Please confirm if the Visit 1 Day 1 Immunogenicity Assessment sample was collected on 21SEP2020 or 21OCT2020 and update CRF as appropriate.' (Site from DM). | (b) (4), (b) (6) | 15 Feb 2021 05:27:07 |
| Query 'Previous query response indicates, "updtad", however, nothing was changed in EDC. Please confirm if the Visit 1 Day 1 Immunogenicity Assessment sample was collected on 21SEP2020 or 21OCT2020 and update CRF as appropriate.' answered with 'date updated to 21 SEP per source records on Visit 1 Day 1' (Site from DM). | (b) (4), (b) (6) | 03 Feb 2021 17:38:57 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 03 Feb 2021 17:38:18 |
| User entered '21 Sep 2020' reason for change: Data Entry Error | (b) (4), (b) (6) | 03 Feb 2021 17:38:18 |
| User opened query 'Previous query response indicates, "updtad", however, nothing was changed in EDC. Please confirm if the Visit 1 Day 1 Immunogenicity Assessment sample was collected on 21SEP2020 or 21OCT2020 and update CRF as appropriate.' (Site from DM). | (b) (4), (b) (6) | 10 Dec 2020 22:24:46 |
| User closed query 'Per GCL Lab Reconciliation Requery: Antibody-mediated Immunogenicity: Please confirm the Month "Oct" recorded for the date of collection 21Oct2020 in EDC as Visit date and sample date in PPD is 21Sep2020 and amend as appropriate or clarify.' (Site from DM). | (b) (4), (b) (6) | 10 Dec 2020 22:24:46 |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Dec 2020 22:08:47 |

US3572330

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:21:46

Collection date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Query 'Per GCL Lab Reconciliation Requery: Antibody-mediated Immunogenicity: Please confirm the Month "Oct" recorded for the date of collection 21Oct2020 in EDC as Visit date and sample date in PPD is 21Sep2020 and amend as appropriate or clarify.' answered with 'updaed' (Site from DM). | (b) (4), (b) (6) | 09 Dec 2020 18:45:52 |
| User opened query 'Per GCL Lab Reconciliation Requery: Antibody-mediated Immunogenicity: Please confirm the Month "Oct" recorded for the date of collection 21Oct2020 in EDC as Visit date and sample date in PPD is 21Sep2020 and amend as appropriate or clarify.' (Site from DM). | (b) (4), (b) (6) | 09 Dec 2020 09:16:27 |
| User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 21Oct2020 is recorded under Visit1 Day1 visit in EDC, however the same is reported under Visit 1 Day1 Visit with date 21Sep2020in 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) | 09 Dec 2020 09:16:27 |
| Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 21Oct2020 is recorded under Visit1 Day1 visit in EDC, however the same is reported under Visit 1 Day1 Visit with date 21Sep2020in PPD Central lab. Please review and confirm the correct date and update as appropriate. Else Clarify, Thank you' answered with 'DATA UPDATED' (Site from DM). | (b) (4), (b) (6) | 08 Dec 2020 21:15:38 |
| User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 21Oct2020 is recorded under Visit1 Day1 visit in EDC, however the same is reported under Visit 1 Day1 Visit with date 21Sep2020in 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) | 17 Nov 2020 14:03:44 |
| Query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' canceled (Site from System). | (b) (4), (b) (6) | 10 Nov 2020 14:07:28 |
| User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System). | System | 28 Oct 2020 01:52:44 |

PRODUCTION RELEASE (v12.003
EAB) (1725)

509 of 1696

US3572330

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:21:46

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------------|----------------------|
| User entered '21 Oct 2020' | Maria Candelario (b) (4) (b) (4) | 28 Oct 2020 01:52:09 |

US3572330

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:21:46

Collection time (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User signature succeeded. | Milton Haber (b) (4) | 21 Mar 2021 00:25:10 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 09 Dec 2020 22:08:47 |
| User entered '10:44' | Maria Candelario (b) (4) (b) (4) | 28 Oct 2020 01:52:09 |

US3572330

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:21:46

[Collection date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User entered '21 Sep 2020 10:44' | System | 03 Feb 2021 17:38:18 |
| User entered '21 Oct 2020 10:44' | System | 28 Oct 2020 01:52:09 |

US3572330

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 08:21:46

Collection date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User signature succeeded. | Milton Haber (b) (4) | 21 Mar 2021 00:25:10 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 09 Dec 2020 22:08:58 |
| User entered '21 Sep 2020' | Maria Candelario (b) (4) (b) (4) | 28 Oct 2020 01:52:27 |

US3572330

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:21:46

[Lab Test](#)

| Audit | User | Time (GMT) |
|--|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)' | Maria Candelario (b) (4) (b) (4) | 28 Oct 2020 01:52:27 |

US3572330

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:21:46

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User signature succeeded. | Milton Haber (b) (4) | 21 Mar 2021 00:25:10 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 09 Dec 2020 22:08:58 |
| User entered 'Yes (Y)' | Maria Candelario (b) (4) (b) (4) | 28 Oct 2020 01:52:27 |

US3572330

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:21:46

Collection time (00:00 - 23:59)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User signature succeeded. | Milton Haber (b) (4) | 21 Mar 2021 00:25:10 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 09 Dec 2020 22:08:58 |
| User entered '10:06' | Maria Candelario (b) (4) (b) (4) | 28 Oct 2020 01:52:27 |

US3572330

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:21:46

[Collection date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User entered '21 Sep 2020 10:06' | System | 28 Oct 2020 01:52:27 |

US3572330

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:21:46

[Lab Test](#)

| Audit | User | Time (GMT) |
|--|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)' | Maria Candelario (b) (4) (b) (4) | 28 Oct 2020 01:52:27 |

US3572330

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:21:46

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User signature succeeded. | Milton Haber (b) (4) | 21 Mar 2021 00:25:10 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 09 Dec 2020 22:08:58 |
| User entered 'No (N)' | Maria Candelario (b) (4) (b) (4) | 28 Oct 2020 01:52:27 |

US3572330

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:21:46

Collection time (00:00 - 23:59)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User signature succeeded. | Milton Haber (b) (4) | 21 Mar 2021 00:25:10 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 09 Dec 2020 22:08:58 |
| User entered empty. | Maria Candelario (b) (4) (b) (4) | 28 Oct 2020 01:52:27 |

US3572330

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:21:46

[Collection date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User entered empty. | System | 28 Oct 2020 01:52:27 |

US3572330

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 08:21:46

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User signature succeeded. | Milton Haber (b) (4) | 21 Mar 2021 00:25:10 |
| DataPoint Verified. | (b) (4) (u) (4), (b) (6) | 09 Dec 2020 22:09:02 |
| User entered 'Yes (Y)' | Martha Bunnell-Pollak (b) (4) | 06 Oct 2020 14:35:09 |

US3572330

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 08:21:46

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User entered 'I' | System | 06 Oct 2020 14:35:09 |

US3572330

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| Data entry locked. | System | 21 Sep 2020 16:59:44 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 21 Sep 2020 16:59:44 |

US3572330

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:21:46

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-09-21T12:02:43', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: '9024fc15-6fb9-47bf-9b82-072eacfb4997' | System | 21 Sep 2020 17:06:05 |
| User entered 'Yes (Y)' | System | 21 Sep 2020 17:06:05 |

US3572330

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:21:46

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-09-21T12:02:50', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: '9024fc15-6fb9-47bf-9b82-072eacfb4997' | System | 21 Sep 2020 17:06:05 |
| User entered '97.3' | System | 21 Sep 2020 17:06:05 |

US3572330

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:21:46

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-09-21T12:02:53', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: '9024fc15-6fb9-47bf-9b82-072eacfb4997' | System | 21 Sep 2020 17:06:05 |
| User entered 'No (N)' | System | 21 Sep 2020 17:06:05 |

US3572330

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:21:46

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-09-21T12:02:58', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: '9024fc15-6fb9-47bf-9b82-072eacfb4997' | System | 21 Sep 2020 17:06:05 |
| User entered '21 Sep 2020 12:02' | System | 21 Sep 2020 17:06:05 |

US3572330

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:21:46

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| User entered '21 Sep 2020 11:42' | System | 21 Sep 2020 16:59:44 |

US3572330

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:21:46

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| User entered '21 Sep 2020 14:12' | System | 21 Sep 2020 16:59:44 |

US3572330

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| Data entry locked. | System | 21 Sep 2020 16:59:44 |
| User entered 'Day 1, after vaccination (at home)' | System | 21 Sep 2020 16:59:44 |

US3572330

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:21:46

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-09-21T19:06:42', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: 'd46dfadc-c4c3-446f-bda4-f4193381fde2' | System | 22 Sep 2020 00:06:57 |
| User entered 'Yes (Y)' | System | 22 Sep 2020 00:06:57 |

US3572330

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:21:46

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-09-21T19:06:49', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: 'd46dfadc-c4c3-446f-bda4-f4193381fde2' | System | 22 Sep 2020 00:06:57 |
| User entered '99.1' | System | 22 Sep 2020 00:06:57 |

US3572330

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:21:46

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-09-21T19:06:52', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: 'd46dfadc-c4c3-446f-bda4-f4193381fde2' | System | 22 Sep 2020 00:06:57 |
| User entered 'No (N)' | System | 22 Sep 2020 00:06:57 |

US3572330

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:21:46

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-09-21T19:06:55', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: 'd46dfadc-c4c3-446f-bda4-f4193381fde2' | System | 22 Sep 2020 00:06:57 |
| User entered '21 Sep 2020 19:06' | System | 22 Sep 2020 00:06:57 |

US3572330

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:21:46

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| User entered '21 Sep 2020 15:07' | System | 21 Sep 2020 16:59:44 |

US3572330

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:21:46

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| User entered '22 Sep 2020 11:59' | System | 21 Sep 2020 16:59:44 |

US3572330

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| Data entry locked. | System | 21 Sep 2020 16:59:44 |
| User entered 'Day 2' | System | 21 Sep 2020 16:59:44 |

US3572330

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:21:46

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-09-22T22:05:22', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: '5f5a937a-2c7d-4c89-82a6-43c68a751fd5' | System | 23 Sep 2020 03:05:38 |
| User entered 'Yes (Y)' | System | 23 Sep 2020 03:05:38 |

US3572330

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:21:46

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-09-22T22:05:27', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: '5f5a937a-2c7d-4c89-82a6-43c68a751fd5' | System | 23 Sep 2020 03:05:38 |
| User entered '99.6' | System | 23 Sep 2020 03:05:38 |

US3572330

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:21:46

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-09-22T22:05:31', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: '5f5a937a-2c7d-4c89-82a6-43c68a751fd5' | System | 23 Sep 2020 03:05:38 |
| User entered 'No (N)' | System | 23 Sep 2020 03:05:38 |

US3572330

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:21:46

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-09-22T22:05:34', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: '5f5a937a-2c7d-4c89-82a6-43c68a751fd5' | System | 23 Sep 2020 03:05:38 |
| User entered '22 Sep 2020 22:05' | System | 23 Sep 2020 03:05:38 |

US3572330

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:21:46

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| User entered '22 Sep 2020 12:00' | System | 21 Sep 2020 16:59:44 |

US3572330

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:21:46

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| User entered '23 Sep 2020 11:59' | System | 21 Sep 2020 16:59:44 |

US3572330

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| Data entry locked. | System | 21 Sep 2020 16:59:44 |
| User entered 'Day 3' | System | 21 Sep 2020 16:59:44 |

US3572330

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:21:46

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-09-23T21:37:20', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: '8e73a54b-3fb2-41f8-b75f-3126b4e0811b' | System | 24 Sep 2020 02:38:09 |
| User entered 'Yes (Y)' | System | 24 Sep 2020 02:38:09 |

US3572330

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:21:46

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-09-23T21:37:51', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: '8e73a54b-3fb2-41f8-b75f-3126b4e0811b' User entered '99.1' | System | 24 Sep 2020 02:38:09 |

US3572330

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:21:46

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-09-23T21:38:00', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: '8e73a54b-3fb2-41f8-b75f-3126b4e0811b' | System | 24 Sep 2020 02:38:09 |
| User entered 'No (N)' | System | 24 Sep 2020 02:38:09 |

US3572330

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:21:46

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-09-23T21:38:02', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: '8e73a54b-3fb2-41f8-b75f-3126b4e0811b' | System | 24 Sep 2020 02:38:09 |
| User entered '23 Sep 2020 21:38' | System | 24 Sep 2020 02:38:09 |

US3572330

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:21:46

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| User entered '23 Sep 2020 12:00' | System | 21 Sep 2020 16:59:44 |

US3572330

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:21:46

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| User entered '24 Sep 2020 11:59' | System | 21 Sep 2020 16:59:44 |

US3572330

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| Data entry locked. | System | 21 Sep 2020 16:59:44 |
| User entered 'Day 4' | System | 21 Sep 2020 16:59:44 |

US3572330

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:21:46

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-09-24T19:45:15', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: '1212634c-1dc2-4ba0-a47b-806b68249e9e' | System | 25 Sep 2020 00:45:30 |
| User entered 'Yes (Y)' | System | 25 Sep 2020 00:45:30 |

US3572330

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:21:46

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-09-24T19:45:20', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: '1212634c-1dc2-4ba0-a47b-806b68249e9e' | System | 25 Sep 2020 00:45:30 |
| User entered '99.0' | System | 25 Sep 2020 00:45:30 |

US3572330

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:21:46

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-09-24T19:45:23', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: '1212634c-1dc2-4ba0-a47b-806b68249e9e' | System | 25 Sep 2020 00:45:30 |
| User entered 'No (N)' | System | 25 Sep 2020 00:45:30 |

US3572330

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:21:46

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-09-24T19:45:28', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: '1212634c-1dc2-4ba0-a47b-806b68249e9e' | System | 25 Sep 2020 00:45:30 |
| User entered '24 Sep 2020 19:45' | System | 25 Sep 2020 00:45:30 |

US3572330

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:21:46

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| User entered '24 Sep 2020 12:00' | System | 21 Sep 2020 16:59:44 |

US3572330

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:21:46

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| User entered '25 Sep 2020 11:59' | System | 21 Sep 2020 16:59:44 |

US3572330

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| Data entry locked. | System | 21 Sep 2020 16:59:44 |
| User entered 'Day 5' | System | 21 Sep 2020 16:59:44 |

US3572330

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:21:46

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-09-26T10:59:45', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: 'eb792b97-a2d9-4295-8e1d-917cd65b1fbb' | System | 26 Sep 2020 16:00:00 |
| User entered 'Yes (Y)' | System | 26 Sep 2020 16:00:00 |

US3572330

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:21:46

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-09-26T10:59:50', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: 'eb792b97-a2d9-4295-8e1d-917cd65b1fbb' | System | 26 Sep 2020 16:00:00 |
| User entered '98.0' | System | 26 Sep 2020 16:00:00 |

US3572330

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:21:46

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-09-26T10:59:52', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: 'eb792b97-a2d9-4295-8e1d-917cd65b1fbb' | System | 26 Sep 2020 16:00:00 |
| User entered 'No (N)' | System | 26 Sep 2020 16:00:00 |

US3572330

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:21:46

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-09-26T10:59:55', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: 'eb792b97-a2d9-4295-8e1d-917cd65b1fbb' | System | 26 Sep 2020 16:00:00 |
| User entered '26 Sep 2020 10:59' | System | 26 Sep 2020 16:00:00 |

US3572330

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:21:46

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| User entered '25 Sep 2020 12:00' | System | 21 Sep 2020 16:59:44 |

US3572330

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:21:46

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| User entered '26 Sep 2020 11:59' | System | 21 Sep 2020 16:59:44 |

US3572330

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| Data entry locked. | System | 21 Sep 2020 16:59:44 |
| User entered 'Day 6' | System | 21 Sep 2020 16:59:44 |

US3572330

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:21:46

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-09-26T19:35:37', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: '6fde2592-3867-43b0-96b3-0581edf54d80' | System | 27 Sep 2020 00:35:55 |
| User entered 'Yes (Y)' | System | 27 Sep 2020 00:35:55 |

US3572330

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:21:46

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-09-26T19:35:42', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: '6fde2592-3867-43b0-96b3-0581edf54d80' | System | 27 Sep 2020 00:35:55 |
| User entered '98.6' | System | 27 Sep 2020 00:35:55 |

US3572330

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:21:46

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-09-26T19:35:45', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: '6fde2592-3867-43b0-96b3-0581edf54d80' | System | 27 Sep 2020 00:35:55 |
| User entered 'No (N)' | System | 27 Sep 2020 00:35:55 |

US3572330

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:21:46

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-09-26T19:35:48', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: '6fde2592-3867-43b0-96b3-0581edf54d80' | System | 27 Sep 2020 00:35:55 |
| User entered '26 Sep 2020 19:35' | System | 27 Sep 2020 00:35:55 |

US3572330

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:21:46

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| User entered '26 Sep 2020 12:00' | System | 21 Sep 2020 16:59:44 |

US3572330

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:21:46

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| User entered '27 Sep 2020 11:59' | System | 21 Sep 2020 16:59:44 |

US3572330

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| Data entry locked. | System | 21 Sep 2020 16:59:44 |
| User entered 'Day 7' | System | 21 Sep 2020 16:59:44 |

US3572330

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:21:46

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |

US3572330

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:21:46

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |

US3572330

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:21:46

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

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |

US3572330

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:21:46

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

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |

US3572330

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:21:46

To **PREVENT** pain or fever from occurring

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |

US3572330

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:21:46

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |

US3572330

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:21:46

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| User entered '27 Sep 2020 12:00' | System | 21 Sep 2020 16:59:44 |

US3572330

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:21:46

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| User entered '28 Sep 2020 11:59' | System | 21 Sep 2020 16:59:44 |

US3572330

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| Data entry locked. | System | 21 Sep 2020 16:59:44 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 21 Sep 2020 16:59:44 |

US3572330

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:21:46

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-09-21T12:03:05', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: 'ae64caa6-f296-44d2-9453-5f3569e8df7a' | System | 21 Sep 2020 17:06:37 |
| User entered 'None (1)' | System | 21 Sep 2020 17:06:37 |

US3572330

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:21:46

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-09-21T12:03:13', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: 'ae64eaa6-f296-44d2-9453-5f3569e8df7a' | System | 21 Sep 2020 17:06:37 |
| User entered 'No (N)' | System | 21 Sep 2020 17:06:37 |

US3572330

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:21:46

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-09-21T12:03:16', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: 'ae64eaa6-f296-44d2-9453-5f3569e8df7a' | System | 21 Sep 2020 17:06:37 |
| User entered 'No (N)' | System | 21 Sep 2020 17:06:37 |

US3572330

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:21:46

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-09-21T12:03:20', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: 'ae64caa6-f296-44d2-9453-5f3569e8df7a' | System | 21 Sep 2020 17:06:37 |
| User entered 'None (1)' | System | 21 Sep 2020 17:06:37 |

US3572330

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:21:46

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-09-21T12:03:23', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: 'ae64eaa6-f296-44d2-9453-5f3569e8df7a' | System | 21 Sep 2020 17:06:37 |
| User entered '21 Sep 2020 12:03' | System | 21 Sep 2020 17:06:37 |

US3572330

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:21:46

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| User entered '21 Sep 2020 11:42' | System | 21 Sep 2020 16:59:44 |

US3572330

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:21:46

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| User entered '21 Sep 2020 14:12' | System | 21 Sep 2020 16:59:44 |

US3572330

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| Data entry locked. | System | 21 Sep 2020 16:59:44 |
| User entered 'Day 1, after vaccination (at home)' | System | 21 Sep 2020 16:59:44 |

US3572330

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:21:46

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-09-21T19:07:07', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: '26473601-ce06-4e88-88f5-510f2d8fcbb0' | System | 22 Sep 2020 00:07:23 |
| User entered 'Does not interfere with activity (2)' | System | 22 Sep 2020 00:07:23 |

US3572330

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:21:46

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-09-21T19:07:10', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: '26473601-ce06-4e88-88f5-510f2d8fcbb0' | System | 22 Sep 2020 00:07:23 |
| User entered 'No (N)' | System | 22 Sep 2020 00:07:23 |

US3572330

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:21:46

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-09-21T19:07:13', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: '26473601-ce06-4e88-88f5-510f2d8fcbb0' | System | 22 Sep 2020 00:07:23 |
| User entered 'No (N)' | System | 22 Sep 2020 00:07:23 |

US3572330

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:21:46

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-09-21T19:07:18', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: '26473601-ce06-4e88-88f5-510f2d8fcbb0' | System | 22 Sep 2020 00:07:23 |
| User entered 'None (1)' | System | 22 Sep 2020 00:07:23 |

US3572330

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:21:46

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-09-21T19:07:21', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: '26473601-ce06-4e88-88f5-510f2d8fcbb0' | System | 22 Sep 2020 00:07:23 |
| User entered '21 Sep 2020 19:07' | System | 22 Sep 2020 00:07:23 |

US3572330

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:21:46

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| User entered '21 Sep 2020 15:07' | System | 21 Sep 2020 16:59:44 |

US3572330

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:21:46

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| User entered '22 Sep 2020 11:59' | System | 21 Sep 2020 16:59:44 |

US3572330

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| Data entry locked. | System | 21 Sep 2020 16:59:44 |
| User entered 'Day 2' | System | 21 Sep 2020 16:59:44 |

US3572330

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:21:46

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-09-22T16:35:32', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: 'f22329aa-8d3a-45dc-a87a-e9b6a0286849' | System | 22 Sep 2020 21:36:13 |
| User entered 'Does not interfere with activity (2)' | System | 22 Sep 2020 21:36:13 |

US3572330

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:21:46

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-09-22T16:35:35', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: 'f22329aa-8d3a-45dc-a87a-e9b6a0286849' | System | 22 Sep 2020 21:36:13 |
| User entered 'Yes (Y)' | System | 22 Sep 2020 21:36:13 |

US3572330

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:21:46

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

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-09-22T16:35:42', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: 'f22329aa-8d3a-45dc-a87a-e9b6a0286849' | System | 22 Sep 2020 21:36:13 |
| User entered '30' | System | 22 Sep 2020 21:36:13 |

US3572330

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:21:46

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-09-22T16:35:46', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: 'f22329aa-8d3a-45dc-a87a-e9b6a0286849' | System | 22 Sep 2020 21:36:13 |
| User entered 'Yes (Y)' | System | 22 Sep 2020 21:36:13 |

US3572330

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:21:46

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

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-09-22T16:35:54', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: 'f22329aa-8d3a-45dc-a87a-e9b6a0286849' | System | 22 Sep 2020 21:36:13 |
| User entered '30' | System | 22 Sep 2020 21:36:13 |

US3572330

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:21:46

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-09-22T16:36:05', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: 'f22329aa-8d3a-45dc-a87a-e9b6a0286849' | System | 22 Sep 2020 21:36:13 |
| User entered 'None (1)' | System | 22 Sep 2020 21:36:13 |

US3572330

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:21:46

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-09-22T16:36:09', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: 'f22329aa-8d3a-45dc-a87a-e9b6a0286849' | System | 22 Sep 2020 21:36:13 |
| User entered '22 Sep 2020 16:36' | System | 22 Sep 2020 21:36:13 |

US3572330

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:21:46

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| User entered '22 Sep 2020 12:00' | System | 21 Sep 2020 16:59:44 |

US3572330

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:21:46

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| User entered '23 Sep 2020 11:59' | System | 21 Sep 2020 16:59:44 |

US3572330

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| Data entry locked. | System | 21 Sep 2020 16:59:44 |
| User entered 'Day 3' | System | 21 Sep 2020 16:59:44 |

US3572330

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:21:46

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-09-23T21:35:53', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: '2d01b1f7-61f4-4035-8754-8a258dafd8ef' | System | 24 Sep 2020 02:36:19 |
| User entered 'Does not interfere with activity (2)' | System | 24 Sep 2020 02:36:19 |

US3572330

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:21:46

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-09-23T21:35:57', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: '2d01b1f7-61f4-4035-8754-8a258dafd8ef' | System | 24 Sep 2020 02:36:19 |
| User entered 'Yes (Y)' | System | 24 Sep 2020 02:36:19 |

US3572330

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:21:46

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

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-09-23T21:36:03', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: '2d01b1f7-61f4-4035-8754-8a258dafd8ef' | System | 24 Sep 2020 02:36:19 |
| User entered '30' | System | 24 Sep 2020 02:36:19 |

US3572330

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:21:46

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-09-23T21:36:06', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: '2d01b1f7-61f4-4035-8754-8a258dafd8ef' | System | 24 Sep 2020 02:36:19 |
| User entered 'Yes (Y)' | System | 24 Sep 2020 02:36:19 |

US3572330

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:21:46

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

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-09-23T21:36:10', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: '2d01b1f7-61f4-4035-8754-8a258dafd8ef' | System | 24 Sep 2020 02:36:19 |
| User entered '30' | System | 24 Sep 2020 02:36:19 |

US3572330

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:21:46

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-09-23T21:36:13', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: '2d01b1f7-61f4-4035-8754-8a258dafd8ef' | System | 24 Sep 2020 02:36:19 |
| User entered 'None (1)' | System | 24 Sep 2020 02:36:19 |

US3572330

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:21:46

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-09-23T21:36:16', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: '2d01b1f7-61f4-4035-8754-8a258dafd8ef' | System | 24 Sep 2020 02:36:19 |
| User entered '23 Sep 2020 21:36' | System | 24 Sep 2020 02:36:19 |

US3572330

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:21:46

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| User entered '23 Sep 2020 12:00' | System | 21 Sep 2020 16:59:44 |

US3572330

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:21:46

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| User entered '24 Sep 2020 11:59' | System | 21 Sep 2020 16:59:44 |

US3572330

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| Data entry locked. | System | 21 Sep 2020 16:59:44 |
| User entered 'Day 4' | System | 21 Sep 2020 16:59:44 |

US3572330

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:21:46

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-09-24T19:45:35', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: '57c91121-6b31-424c-9237-cc2e51bf8880' | System | 25 Sep 2020 00:46:00 |
| User entered 'Does not interfere with activity (2)' | System | 25 Sep 2020 00:46:00 |

US3572330

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:21:46

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-09-24T19:45:38', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: '57c91121-6b31-424c-9237-cc2e51bf8880' | System | 25 Sep 2020 00:46:00 |
| User entered 'Yes (Y)' | System | 25 Sep 2020 00:46:00 |

US3572330

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:21:46

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

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-09-24T19:45:45', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: '57c91121-6b31-424c-9237-cc2e51bf8880' | System | 25 Sep 2020 00:46:00 |
| User entered '20' | System | 25 Sep 2020 00:46:00 |

US3572330

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:21:46

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-09-24T19:45:48', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: '57c91121-6b31-424c-9237-cc2e51bf8880' | System | 25 Sep 2020 00:46:00 |
| User entered 'Yes (Y)' | System | 25 Sep 2020 00:46:00 |

US3572330

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:21:46

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

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-09-24T19:45:51', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: '57c91121-6b31-424c-9237-cc2e51bf8880' | System | 25 Sep 2020 00:46:00 |
| User entered '20' | System | 25 Sep 2020 00:46:00 |

US3572330

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:21:46

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-09-24T19:45:54', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: '57c91121-6b31-424c-9237-cc2e51bf8880' | System | 25 Sep 2020 00:46:00 |
| User entered 'None (1)' | System | 25 Sep 2020 00:46:00 |

US3572330

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:21:46

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-09-24T19:45:57', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: '57c91121-6b31-424c-9237-cc2e51bf8880' | System | 25 Sep 2020 00:46:00 |
| User entered '24 Sep 2020 19:45' | System | 25 Sep 2020 00:46:00 |

US3572330

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:21:46

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| User entered '24 Sep 2020 12:00' | System | 21 Sep 2020 16:59:44 |

US3572330

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:21:46

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| User entered '25 Sep 2020 11:59' | System | 21 Sep 2020 16:59:44 |

US3572330

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| Data entry locked. | System | 21 Sep 2020 16:59:44 |
| User entered 'Day 5' | System | 21 Sep 2020 16:59:44 |

US3572330

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:21:46

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-09-26T11:00:05', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: '114a890c-35f0-4311-9281-b0fd6ee45da8' | System | 26 Sep 2020 16:00:40 |
| User entered 'None (1)' | System | 26 Sep 2020 16:00:40 |

US3572330

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:21:46

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-09-26T11:00:15', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: '114a890c-35f0-4311-9281-b0fd6ee45da8' | System | 26 Sep 2020 16:00:40 |
| User entered 'Yes (Y)' | System | 26 Sep 2020 16:00:40 |

US3572330

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:21:46

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

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-09-26T11:00:18', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: '114a890c-35f0-4311-9281-b0fd6ee45da8' | System | 26 Sep 2020 16:00:40 |
| User entered '10' | System | 26 Sep 2020 16:00:40 |

US3572330

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:21:46

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-09-26T11:00:21', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: '114a890c-35f0-4311-9281-b0fd6ee45da8' | System | 26 Sep 2020 16:00:40 |
| User entered 'No (N)' | System | 26 Sep 2020 16:00:40 |

US3572330

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:21:46

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-09-26T11:00:23', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: '114a890c-35f0-4311-9281-b0fd6ee45da8' | System | 26 Sep 2020 16:00:40 |
| User entered 'None (1)' | System | 26 Sep 2020 16:00:40 |

US3572330

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:21:46

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-09-26T11:00:26', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: '114a890c-35f0-4311-9281-b0fd6ee45da8' | System | 26 Sep 2020 16:00:40 |
| User entered '26 Sep 2020 11:00' | System | 26 Sep 2020 16:00:40 |

US3572330

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:21:46

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| User entered '25 Sep 2020 12:00' | System | 21 Sep 2020 16:59:44 |

US3572330

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:21:46

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| User entered '26 Sep 2020 11:59' | System | 21 Sep 2020 16:59:44 |

US3572330

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| Data entry locked. | System | 21 Sep 2020 16:59:44 |
| User entered 'Day 6' | System | 21 Sep 2020 16:59:44 |

US3572330

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:21:46

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-09-26T19:35:52', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: '0a34d619-2035-499e-9858-5dd1c2ecfa45' | System | 27 Sep 2020 00:36:08 |
| User entered 'None (1)' | System | 27 Sep 2020 00:36:08 |

US3572330

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:21:46

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-09-26T19:35:54', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: '0a34d619-2035-499e-9858-5dd1c2ecfa45' | System | 27 Sep 2020 00:36:08 |
| User entered 'No (N)' | System | 27 Sep 2020 00:36:08 |

US3572330

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:21:46

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-09-26T19:36:00', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: '0a34d619-2035-499e-9858-5dd1c2ecfa45' | System | 27 Sep 2020 00:36:08 |
| User entered 'No (N)' | System | 27 Sep 2020 00:36:08 |

US3572330

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:21:46

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-09-26T19:36:02', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: '0a34d619-2035-499e-9858-5dd1c2ecfa45' | System | 27 Sep 2020 00:36:08 |
| User entered 'None (1)' | System | 27 Sep 2020 00:36:08 |

US3572330

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:21:46

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-09-26T19:36:05', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: '0a34d619-2035-499e-9858-5dd1c2ecfa45' | System | 27 Sep 2020 00:36:08 |
| User entered '26 Sep 2020 19:36' | System | 27 Sep 2020 00:36:08 |

US3572330

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:21:46

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| User entered '26 Sep 2020 12:00' | System | 21 Sep 2020 16:59:44 |

US3572330

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:21:46

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| User entered '27 Sep 2020 11:59' | System | 21 Sep 2020 16:59:44 |

US3572330

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| Data entry locked. | System | 21 Sep 2020 16:59:44 |
| User entered 'Day 7' | System | 21 Sep 2020 16:59:44 |

US3572330

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:21:46

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

Please select one response below

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |

US3572330

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:21:46

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |

US3572330

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:21:46

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

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

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |

US3572330

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:21:46

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

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |

US3572330

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:21:46

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

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

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |

US3572330

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:21:46

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

Please select one response below

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |

US3572330

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:21:46

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |

US3572330

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:21:46

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| User entered '27 Sep 2020 12:00' | System | 21 Sep 2020 16:59:44 |

US3572330

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:21:46

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| User entered '28 Sep 2020 11:59' | System | 21 Sep 2020 16:59:44 |

US3572330

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| Data entry locked. | System | 21 Sep 2020 16:59:44 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 21 Sep 2020 16:59:44 |

US3572330

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:21:46

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-09-21T12:05:04', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: '72746611-e616-462d-8e99-a876757bd90e' | System | 21 Sep 2020 17:07:40 |
| User entered 'None (0)' | System | 21 Sep 2020 17:07:40 |

US3572330

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:21:46

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-09-21T12:05:09', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: '72746611-e616-462d-8e99-a876757bd90e' | System | 21 Sep 2020 17:07:40 |
| User entered 'None (0)' | System | 21 Sep 2020 17:07:40 |

US3572330

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:21:46

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-09-21T12:05:11', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: '72746611-e616-462d-8e99-a876757bd90e' | System | 21 Sep 2020 17:07:40 |
| User entered 'None (0)' | System | 21 Sep 2020 17:07:40 |

US3572330

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:21:46

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-09-21T12:05:14', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: '72746611-e616-462d-8e99-a876757bd90e' | System | 21 Sep 2020 17:07:40 |
| User entered 'None (0)' | System | 21 Sep 2020 17:07:40 |

US3572330

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:21:46

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-09-21T12:05:17', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: '72746611-e616-462d-8e99-a876757bd90e' | System | 21 Sep 2020 17:07:40 |
| User entered 'None (0)' | System | 21 Sep 2020 17:07:40 |

US3572330

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:21:46

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-09-21T12:05:19', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: '72746611-e616-462d-8e99-a876757bd90e' | System | 21 Sep 2020 17:07:40 |
| User entered 'None (0)' | System | 21 Sep 2020 17:07:40 |

US3572330

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:21:46

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-09-21T12:05:26', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: '72746611-e616-462d-8e99-a876757bd90e' | System | 21 Sep 2020 17:07:40 |
| User entered 'No (N)' | System | 21 Sep 2020 17:07:40 |

US3572330

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:21:46

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-09-21T12:05:28', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: '72746611-e616-462d-8e99-a876757bd90e' | System | 21 Sep 2020 17:07:40 |
| User entered '21 Sep 2020 12:05' | System | 21 Sep 2020 17:07:40 |

US3572330

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:21:46

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| User entered '21 Sep 2020 11:42' | System | 21 Sep 2020 16:59:44 |

US3572330

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:21:46

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| User entered '21 Sep 2020 14:12' | System | 21 Sep 2020 16:59:44 |

US3572330

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| Data entry locked. | System | 21 Sep 2020 16:59:44 |
| User entered 'Day 1, after vaccination (at home)' | System | 21 Sep 2020 16:59:44 |

US3572330

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:21:46

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-09-21T19:07:30', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: '92fe9523-23f3-419e-8a08-40e0adb04b5e' | System | 22 Sep 2020 00:08:15 |
| User entered 'None (0)' | System | 22 Sep 2020 00:08:15 |

US3572330

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:21:46

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-09-21T19:07:33', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: '92fe9523-23f3-419e-8a08-40e0adb04b5e' | System | 22 Sep 2020 00:08:15 |
| User entered 'None (0)' | System | 22 Sep 2020 00:08:15 |

US3572330

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:21:46

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-09-21T19:07:36', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: '92fe9523-23f3-419e-8a08-40e0adb04b5e' | System | 22 Sep 2020 00:08:15 |
| User entered 'None (0)' | System | 22 Sep 2020 00:08:15 |

US3572330

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:21:46

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-09-21T19:07:39', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: '92fe9523-23f3-419e-8a08-40e0adb04b5e' | System | 22 Sep 2020 00:08:15 |
| User entered 'None (0)' | System | 22 Sep 2020 00:08:15 |

US3572330

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:21:46

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-09-21T19:07:41', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: '92fe9523-23f3-419e-8a08-40e0adb04b5e' | System | 22 Sep 2020 00:08:15 |
| User entered 'None (0)' | System | 22 Sep 2020 00:08:15 |

US3572330

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:21:46

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-09-21T19:07:44', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: '92fe9523-23f3-419e-8a08-40e0adb04b5e' | System | 22 Sep 2020 00:08:15 |
| User entered 'None (0)' | System | 22 Sep 2020 00:08:15 |

US3572330

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:21:46

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-09-21T19:08:09', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: '92fe9523-23f3-419e-8a08-40e0adb04b5e' | System | 22 Sep 2020 00:08:15 |
| User entered 'No (N)' | System | 22 Sep 2020 00:08:15 |

US3572330

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:21:46

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-09-21T19:08:12', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: '92fe9523-23f3-419e-8a08-40e0adb04b5e' | System | 22 Sep 2020 00:08:15 |
| User entered '21 Sep 2020 19:08' | System | 22 Sep 2020 00:08:15 |

US3572330

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:21:46

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| User entered '21 Sep 2020 15:07' | System | 21 Sep 2020 16:59:44 |

US3572330

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:21:46

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| User entered '22 Sep 2020 11:59' | System | 21 Sep 2020 16:59:44 |

US3572330

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| Data entry locked. | System | 21 Sep 2020 16:59:44 |
| User entered 'Day 2' | System | 21 Sep 2020 16:59:44 |

US3572330

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:21:46

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-09-22T16:36:19', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: '27b86157-4cbc-4a10-95dc-8d721ce9b20b' | System | 22 Sep 2020 21:36:57 |
| User entered 'None (0)' | System | 22 Sep 2020 21:36:57 |

US3572330

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:21:46

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-09-22T16:36:22', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: '27b86157-4cbc-4a10-95dc-8d721ce9b20b' | System | 22 Sep 2020 21:36:57 |
| User entered 'No interference with activity (1)' | System | 22 Sep 2020 21:36:57 |

US3572330

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:21:46

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-09-22T16:36:26', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: '27b86157-4cbc-4a10-95dc-8d721ce9b20b' | System | 22 Sep 2020 21:36:57 |
| User entered 'None (0)' | System | 22 Sep 2020 21:36:57 |

US3572330

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:21:46

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-09-22T16:36:29', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: '27b86157-4cbc-4a10-95dc-8d721ce9b20b' | System | 22 Sep 2020 21:36:57 |
| User entered 'None (0)' | System | 22 Sep 2020 21:36:57 |

US3572330

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:21:46

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-09-22T16:36:32', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: '27b86157-4cbc-4a10-95dc-8d721ce9b20b' | System | 22 Sep 2020 21:36:57 |
| User entered 'None (0)' | System | 22 Sep 2020 21:36:57 |

US3572330

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:21:46

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-09-22T16:36:35', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: '27b86157-4cbc-4a10-95dc-8d721ce9b20b' | System | 22 Sep 2020 21:36:57 |
| User entered 'None (0)' | System | 22 Sep 2020 21:36:57 |

US3572330

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:21:46

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-09-22T16:36:39', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: '27b86157-4cbc-4a10-95dc-8d721ce9b20b' | System | 22 Sep 2020 21:36:57 |
| User entered 'No (N)' | System | 22 Sep 2020 21:36:57 |

US3572330

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:21:46

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-09-22T16:36:42', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: '27b86157-4cbc-4a10-95dc-8d721ce9b20b' | System | 22 Sep 2020 21:36:57 |
| User entered '22 Sep 2020 16:36' | System | 22 Sep 2020 21:36:57 |

US3572330

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:21:46

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| User entered '22 Sep 2020 12:00' | System | 21 Sep 2020 16:59:44 |

US3572330

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:21:46

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| User entered '23 Sep 2020 11:59' | System | 21 Sep 2020 16:59:44 |

US3572330

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| Data entry locked. | System | 21 Sep 2020 16:59:44 |
| User entered 'Day 3' | System | 21 Sep 2020 16:59:44 |

US3572330

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:21:46

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-09-23T21:35:17', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: 'cb42ae6f-9c2c-403a-90ce-616c88cdefb8' | System | 24 Sep 2020 02:35:50 |
| User entered 'None (0)' | System | 24 Sep 2020 02:35:50 |

US3572330

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:21:46

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-09-23T21:35:20', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: 'cb42ae6f-9c2c-403a-90ce-616c88cdefb8' | System | 24 Sep 2020 02:35:50 |
| User entered 'No interference with activity (1)' | System | 24 Sep 2020 02:35:50 |

US3572330

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:21:46

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-09-23T21:35:26', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: 'cb42ae6f-9c2c-403a-90ce-616c88cdefb8' | System | 24 Sep 2020 02:35:50 |
| User entered 'Some interference with activity (2)' | System | 24 Sep 2020 02:35:50 |

US3572330

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:21:46

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-09-23T21:35:34', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: 'cb42ae6f-9c2c-403a-90ce-616c88cdefb8' | System | 24 Sep 2020 02:35:50 |
| User entered 'No interference with activity (1)' | System | 24 Sep 2020 02:35:50 |

US3572330

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:21:46

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-09-23T21:35:37', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: 'cb42ae6f-9c2c-403a-90ce-616c88cdefb8' | System | 24 Sep 2020 02:35:50 |
| User entered 'None (0)' | System | 24 Sep 2020 02:35:50 |

US3572330

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:21:46

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-09-23T21:35:39', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: 'cb42ae6f-9c2c-403a-90ce-616c88cdefb8' | System | 24 Sep 2020 02:35:50 |
| User entered 'None (0)' | System | 24 Sep 2020 02:35:50 |

US3572330

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:21:46

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-09-23T21:35:42', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: 'cb42ae6f-9c2c-403a-90ce-616c88cdefb8' | System | 24 Sep 2020 02:35:50 |
| User entered 'No (N)' | System | 24 Sep 2020 02:35:50 |

US3572330

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:21:46

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-09-23T21:35:44', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: 'cb42ae6f-9c2c-403a-90ce-616c88cdefb8' | System | 24 Sep 2020 02:35:50 |
| User entered '23 Sep 2020 21:35' | System | 24 Sep 2020 02:35:50 |

US3572330

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:21:46

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| User entered '23 Sep 2020 12:00' | System | 21 Sep 2020 16:59:44 |

US3572330

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:21:46

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| User entered '24 Sep 2020 11:59' | System | 21 Sep 2020 16:59:44 |

US3572330

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| Data entry locked. | System | 21 Sep 2020 16:59:44 |
| User entered 'Day 4' | System | 21 Sep 2020 16:59:44 |

US3572330

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:21:46

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-09-24T19:46:01', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: '5ee384c5-b1d7-4fef-be1d-e78cf36bc7c8' | System | 25 Sep 2020 00:46:26 |
| User entered 'None (0)' | System | 25 Sep 2020 00:46:26 |

US3572330

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:21:46

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-09-24T19:46:04', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: '5ee384c5-b1d7-4fef-be1d-e78cf36bc7c8' | System | 25 Sep 2020 00:46:26 |
| User entered 'None (0)' | System | 25 Sep 2020 00:46:26 |

US3572330

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:21:46

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-09-24T19:46:07', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: '5ee384c5-b1d7-4fef-be1d-e78cf36bc7c8' | System | 25 Sep 2020 00:46:26 |
| User entered 'None (0)' | System | 25 Sep 2020 00:46:26 |

US3572330

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:21:46

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-09-24T19:46:10', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: '5ee384c5-b1d7-4fef-be1d-e78cf36bc7c8' | System | 25 Sep 2020 00:46:26 |
| User entered 'None (0)' | System | 25 Sep 2020 00:46:26 |

US3572330

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:21:46

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-09-24T19:46:13', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: '5ee384c5-b1d7-4fef-be1d-e78cf36bc7c8' | System | 25 Sep 2020 00:46:26 |
| User entered 'None (0)' | System | 25 Sep 2020 00:46:26 |

US3572330

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:21:46

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-09-24T19:46:15', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: '5ee384c5-b1d7-4fef-be1d-e78cf36bc7c8' | System | 25 Sep 2020 00:46:26 |
| User entered 'None (0)' | System | 25 Sep 2020 00:46:26 |

US3572330

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:21:46

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-09-24T19:46:20', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: '5ee384c5-b1d7-4fef-be1d-e78cf36bc7c8' | System | 25 Sep 2020 00:46:26 |
| User entered 'No (N)' | System | 25 Sep 2020 00:46:26 |

US3572330

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:21:46

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-09-24T19:46:22', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: '5ee384c5-b1d7-4fef-be1d-e78cf36bc7c8' | System | 25 Sep 2020 00:46:26 |
| User entered '24 Sep 2020 19:46' | System | 25 Sep 2020 00:46:26 |

US3572330

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:21:46

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| User entered '24 Sep 2020 12:00' | System | 21 Sep 2020 16:59:44 |

US3572330

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:21:46

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| User entered '25 Sep 2020 11:59' | System | 21 Sep 2020 16:59:44 |

US3572330

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| Data entry locked. | System | 21 Sep 2020 16:59:44 |
| User entered 'Day 5' | System | 21 Sep 2020 16:59:44 |

US3572330

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:21:46

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-09-26T11:00:30', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: '34b0f04e-f456-4351-b8a7-b596ae98c240' | System | 26 Sep 2020 16:01:21 |
| User entered 'None (0)' | System | 26 Sep 2020 16:01:21 |

US3572330

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:21:46

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-09-26T11:00:32', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: '34b0f04e-f456-4351-b8a7-b596ae98c240' | System | 26 Sep 2020 16:01:21 |
| User entered 'None (0)' | System | 26 Sep 2020 16:01:21 |

US3572330

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:21:46

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-09-26T11:00:34', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: '34b0f04e-f456-4351-b8a7-b596ae98c240' | System | 26 Sep 2020 16:01:21 |
| User entered 'None (0)' | System | 26 Sep 2020 16:01:21 |

US3572330

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:21:46

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-09-26T11:00:37', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: '34b0f04e-f456-4351-b8a7-b596ae98c240' | System | 26 Sep 2020 16:01:21 |
| User entered 'None (0)' | System | 26 Sep 2020 16:01:21 |

US3572330

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:21:46

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-09-26T11:00:39', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: '34b0f04e-f456-4351-b8a7-b596ae98c240' | System | 26 Sep 2020 16:01:21 |
| User entered 'None (0)' | System | 26 Sep 2020 16:01:21 |

US3572330

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:21:46

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-09-26T11:00:41', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: '34b0f04e-f456-4351-b8a7-b596ae98c240' | System | 26 Sep 2020 16:01:21 |
| User entered 'None (0)' | System | 26 Sep 2020 16:01:21 |

US3572330

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:21:46

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-09-26T11:00:45', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: '34b0f04e-f456-4351-b8a7-b596ae98c240' | System | 26 Sep 2020 16:01:21 |
| User entered 'No (N)' | System | 26 Sep 2020 16:01:21 |

US3572330

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:21:46

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-09-26T11:00:49', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: '34b0f04e-f456-4351-b8a7-b596ae98c240' | System | 26 Sep 2020 16:01:21 |
| User entered '26 Sep 2020 11:00' | System | 26 Sep 2020 16:01:21 |

US3572330

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:21:46

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| User entered '25 Sep 2020 12:00' | System | 21 Sep 2020 16:59:44 |

US3572330

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:21:46

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| User entered '26 Sep 2020 11:59' | System | 21 Sep 2020 16:59:44 |

US3572330

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| Data entry locked. | System | 21 Sep 2020 16:59:44 |
| User entered 'Day 6' | System | 21 Sep 2020 16:59:44 |

US3572330

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:21:46

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-09-26T19:36:09', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: '56e8cf5f-96b7-4dd9-b95f-63643dd2137b' | System | 27 Sep 2020 00:36:36 |
| User entered 'None (0)' | System | 27 Sep 2020 00:36:36 |

US3572330

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:21:46

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-09-26T19:36:14', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: '56e8cf5f-96b7-4dd9-b95f-63643dd2137b' | System | 27 Sep 2020 00:36:36 |
| User entered 'No interference with activity (1)' | System | 27 Sep 2020 00:36:36 |

US3572330

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:21:46

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-09-26T19:36:16', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: '56e8cf5f-96b7-4dd9-b95f-63643dd2137b' | System | 27 Sep 2020 00:36:36 |
| User entered 'None (0)' | System | 27 Sep 2020 00:36:36 |

US3572330

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:21:46

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-09-26T19:36:17', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: '56e8cf5f-96b7-4dd9-b95f-63643dd2137b' | System | 27 Sep 2020 00:36:36 |
| User entered 'None (0)' | System | 27 Sep 2020 00:36:36 |

US3572330

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:21:46

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-09-26T19:36:19', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: '56e8cf5f-96b7-4dd9-b95f-63643dd2137b' | System | 27 Sep 2020 00:36:36 |
| User entered 'None (0)' | System | 27 Sep 2020 00:36:36 |

US3572330

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:21:46

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-09-26T19:36:21', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: '56e8cf5f-96b7-4dd9-b95f-63643dd2137b' | System | 27 Sep 2020 00:36:36 |
| User entered 'None (0)' | System | 27 Sep 2020 00:36:36 |

US3572330

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:21:46

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-09-26T19:36:24', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: '56e8cf5f-96b7-4dd9-b95f-63643dd2137b' | System | 27 Sep 2020 00:36:36 |
| User entered 'No (N)' | System | 27 Sep 2020 00:36:36 |

US3572330

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:21:46

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-09-26T19:36:31', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: '56e8cf5f-96b7-4dd9-b95f-63643dd2137b' | System | 27 Sep 2020 00:36:36 |
| User entered '26 Sep 2020 19:36' | System | 27 Sep 2020 00:36:36 |

US3572330

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:21:46

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| User entered '26 Sep 2020 12:00' | System | 21 Sep 2020 16:59:44 |

US3572330

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:21:46

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| User entered '27 Sep 2020 11:59' | System | 21 Sep 2020 16:59:44 |

US3572330

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| Data entry locked. | System | 21 Sep 2020 16:59:44 |
| User entered 'Day 7' | System | 21 Sep 2020 16:59:44 |

US3572330

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:21:46

HEADACHE

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |

US3572330

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:21:46

FATIGUE

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |

US3572330

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:21:46

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |

US3572330

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:21:46

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |

US3572330

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:21:46

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |

US3572330

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:21:46

CHILLS

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |

US3572330

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:21:46

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

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |

US3572330

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:21:46

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |

US3572330

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:21:46

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| User entered '27 Sep 2020 12:00' | System | 21 Sep 2020 16:59:44 |

US3572330

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:21:46

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| User entered '28 Sep 2020 11:59' | System | 21 Sep 2020 16:59:44 |

US3572330

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| Data entry locked. | System | 27 Sep 2020 00:36:36 |
| User entered 'Day 8' | System | 27 Sep 2020 00:36:36 |

US3572330

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 10 Jun 2021 08:21:46

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-09-28T14:51:27', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: '9eee3202-d0dd-42dd-9e1b-e891f2457de9' | System | 28 Sep 2020 19:51:36 |
| User entered 'No interference with activity (1)' | System | 28 Sep 2020 19:51:36 |

US3572330

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 10 Jun 2021 08:21:46

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-09-28T14:51:32', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: '9eee3202-d0dd-42dd-9e1b-e891f2457de9' | System | 28 Sep 2020 19:51:36 |
| User entered '28 Sep 2020 14:51' | System | 28 Sep 2020 19:51:36 |

US3572330

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 10 Jun 2021 08:21:46

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| User entered '28 Sep 2020 12:00' | System | 27 Sep 2020 00:36:36 |

US3572330

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 10 Jun 2021 08:21:46

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| User entered '29 Sep 2020 11:59' | System | 27 Sep 2020 00:36:36 |

US3572330

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| Data entry locked. | System | 28 Sep 2020 19:51:36 |
| User entered 'Day 9' | System | 28 Sep 2020 19:51:36 |

US3572330

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 10 Jun 2021 08:21:46

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

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |

US3572330

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 10 Jun 2021 08:21:46

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |

US3572330

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 10 Jun 2021 08:21:46

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| User entered '29 Sep 2020 12:00' | System | 28 Sep 2020 19:51:36 |

US3572330

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 10 Jun 2021 08:21:46

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| User entered '30 Sep 2020 11:59' | System | 28 Sep 2020 19:51:36 |

US3572330

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| Data entry locked. | System | 28 Sep 2020 19:51:36 |
| User entered 'Day 10' | System | 28 Sep 2020 19:51:36 |

US3572330

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 10 Jun 2021 08:21:46

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-09-30T14:11:33', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: '8ee55719-2eb6-4833-9298-8763b6202bf1' | System | 30 Sep 2020 19:11:37 |
| User entered 'None (0)' | System | 30 Sep 2020 19:11:37 |

US3572330

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 10 Jun 2021 08:21:46

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-09-30T14:11:35', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: '8ee55719-2eb6-4833-9298-8763b6202bf1' | System | 30 Sep 2020 19:11:37 |
| User entered '30 Sep 2020 14:11' | System | 30 Sep 2020 19:11:37 |

US3572330

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 10 Jun 2021 08:21:46

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| User entered '30 Sep 2020 12:00' | System | 28 Sep 2020 19:51:36 |

US3572330

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 10 Jun 2021 08:21:46

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| User entered '01 Oct 2020 11:59' | System | 28 Sep 2020 19:51:36 |

US3572330

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| Data entry locked. | System | 27 Sep 2020 00:36:36 |
| User entered 'Day 8' | System | 27 Sep 2020 00:36:36 |

US3572330

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 08:21:46

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

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-09-28T14:51:36', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: 'b0b08349-2f91-44db-af3-120b680a06cd' | System | 28 Sep 2020 19:51:45 |
| User entered 'No (N)' | System | 28 Sep 2020 19:51:45 |

US3572330

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 08:21:46

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-09-28T14:51:39', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: 'b0b08349-2f91-44db-ae3f-120b680a06cd' | System | 28 Sep 2020 19:51:45 |
| User entered '28 Sep 2020 14:51' | System | 28 Sep 2020 19:51:45 |

US3572330

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 08:21:46

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| User entered '28 Sep 2020 12:00' | System | 27 Sep 2020 00:36:36 |

US3572330

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 08:21:46

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| User entered '29 Sep 2020 11:59' | System | 27 Sep 2020 00:36:36 |

US3572330

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| Data entry locked. | System | 28 Sep 2020 19:51:36 |
| User entered 'Day 9' | System | 28 Sep 2020 19:51:36 |

US3572330

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 08:21:46

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

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |

US3572330

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 08:21:46

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |

US3572330

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 08:21:46

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| User entered '29 Sep 2020 12:00' | System | 28 Sep 2020 19:51:36 |

US3572330

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 08:21:46

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| User entered '30 Sep 2020 11:59' | System | 28 Sep 2020 19:51:36 |

US3572330

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| Data entry locked. | System | 28 Sep 2020 19:51:36 |
| User entered 'Day 10' | System | 28 Sep 2020 19:51:36 |

US3572330

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 10 Jun 2021 08:21:46

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-09-30T14:11:39', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: '88f0e0a5-759c-48c7-a622-f4950e8ea6df' | System | 30 Sep 2020 19:11:44 |
| User entered 'No (N)' | System | 30 Sep 2020 19:11:44 |

US3572330

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 10 Jun 2021 08:21:46

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-09-30T14:11:41', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: '88f0e0a5-759c-48c7-a622-f4950e8ea6df' | System | 30 Sep 2020 19:11:44 |
| User entered '30 Sep 2020 14:11' | System | 30 Sep 2020 19:11:44 |

US3572330

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 10 Jun 2021 08:21:46

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| User entered '30 Sep 2020 12:00' | System | 28 Sep 2020 19:51:36 |

US3572330

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 10 Jun 2021 08:21:46

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| User entered '01 Oct 2020 11:59' | System | 28 Sep 2020 19:51:36 |

US3572330

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:21:46

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User signature succeeded. | Milton Haber (b) (4) | 21 Mar 2021 00:25:10 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 10 Dec 2020 20:34:16 |
| User entered 'Yes (Y)' | Martha Bunnell-Pollak (b) (4) | 06 Oct 2020 14:35:44 |

US3572330

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:21:46

Date of Contact or Contact Attempt (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 11 Apr 2021 22:26:23 |
| User signature succeeded. | Milton Haber (b) (4) | 21 Mar 2021 00:25:10 |
| User closed query 'Per source, 28Sep20 is noted. Please reconcile.' (Site from CRA). | (b) (4) | |
| Query 'Per source, 28Sep20 is noted. Please reconcile.' answered with 'date corrected per source' (Site from CRA). | (b) (4), (b) (6) | 22 Feb 2021 10:14:38 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 02 Feb 2021 19:52:51 |
| User entered '28 Sep 2020' reason for change: Data Entry Error | (b) (4), (b) (6) | 02 Feb 2021 19:52:33 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Dec 2020 20:34:16 |
| User opened query 'Per source, 28Sep20 is noted. Please reconcile.' (Site from CRA). | (b) (4), (b) (6) | 10 Dec 2020 20:34:14 |
| User entered '29 Sep 2020' | Martha Bunnell-Pollak (b) (4) | 06 Oct 2020 14:35:44 |

US3572330

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:21:46

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User signature succeeded. | Milton Haber (b) (4) | 21 Mar 2021 00:25:10 |
| DataPoint Verified. | (b) (4) (u) (4), (b) (6) | 10 Dec 2020 20:34:16 |
| User entered 'Contact Made (CONTACT MADE)' | Martha Bunnell-Pollak (b) (4) | 06 Oct 2020 14:35:44 |

US3572330

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:21:46

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User signature succeeded. | Milton Haber (b) (4) | 21 Mar 2021 00:25:10 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 10 Dec 2020 20:34:16 |
| User entered empty. | Martha Bunnell-Pollak (b) (4) | 06 Oct 2020 14:35:44 |

US3572330

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:21:46

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User signature succeeded. | Milton Haber (b) (4) | 21 Mar 2021 00:25:10 |
| DataPoint Verified. | (b) (4) (u) (4), (b) (6) | 10 Dec 2020 20:34:23 |
| User entered 'Yes (Y)' | Martha Bunnell-Pollak (b) (4) | 06 Oct 2020 14:35:52 |

US3572330

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:21:46

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User entered 'l' | System | 06 Oct 2020 14:35:52 |

US3572330

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:21:46

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User signature succeeded. | Milton Haber (b) (4) | 21 Mar 2021 00:25:10 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 10 Dec 2020 20:34:47 |
| User entered 'Yes (Y)' | Martha Bunnell-Pollak (b) (4) | 06 Oct 2020 14:36:07 |

US3572330

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:21:46

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

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User signature succeeded. | Milton Haber (b) (4) | 21 Mar 2021 00:25:10 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 10 Dec 2020 20:34:47 |
| User entered '6 Oct 2020' | Martha Bunnell-Pollak (b) (4) | 06 Oct 2020 14:36:07 |

US3572330

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:21:46

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User signature succeeded. | Milton Haber (b) (4) | 21 Mar 2021 00:25:10 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 10 Dec 2020 20:34:47 |
| User entered 'Contact Made (CONTACT MADE)' | Martha Bunnell-Pollak (b) (4) | 06 Oct 2020 14:36:07 |

US3572330

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:21:46

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User signature succeeded. | Milton Haber (b) (4) | 21 Mar 2021 00:25:10 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 10 Dec 2020 20:34:47 |
| User entered empty. | Martha Bunnell-Pollak (b) (4) | 06 Oct 2020 14:36:07 |

US3572330

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:21:46

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User signature succeeded. | Milton Haber (b) (4) | 21 Mar 2021 00:25:10 |
| DataPoint Verified. | (b) (4) (u) (4), (b) (6) | 10 Dec 2020 20:34:51 |
| User entered 'Yes (Y)' | Martha Bunnell-Pollak (b) (4) | 06 Oct 2020 14:36:11 |

US3572330

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:21:46

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User entered 'l' | System | 06 Oct 2020 14:36:11 |

US3572330

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:21:46

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User signature succeeded. | Milton Haber (b) (4) | 21 Mar 2021 00:25:10 |
| DataPoint Verified. | (b) (4) (u) (4), (b) (6) | 10 Dec 2020 20:35:50 |
| User entered 'Yes (Y)' | Martha Bunnell-Pollak (b) (4) | 12 Oct 2020 17:13:58 |

US3572330

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:21:46

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

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User signature succeeded. | Milton Haber (b) (4) | 21 Mar 2021 00:25:10 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 10 Dec 2020 20:35:50 |
| User entered '12 Oct 2020' | Martha Bunnell-Pollak (b) (4) | 12 Oct 2020 17:13:58 |

US3572330

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:21:46

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User signature succeeded. | Milton Haber (b) (4) | 21 Mar 2021 00:25:10 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 10 Dec 2020 20:35:50 |
| User entered 'Contact Made (CONTACT MADE)' | Martha Bunnell-Pollak (b) (4) | 12 Oct 2020 17:13:58 |

US3572330

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:21:46

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User signature succeeded. | Milton Haber (b) (4) | 21 Mar 2021 00:25:10 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 10 Dec 2020 20:35:50 |
| User entered empty. | Martha Bunnell-Pollak (b) (4) | 12 Oct 2020 17:13:58 |

US3572330

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:21:46

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User signature succeeded. | Milton Haber (b) (4) | 21 Mar 2021 00:25:10 |
| DataPoint Verified. | (b) (4) (u) (4), (b) (6) | 10 Dec 2020 20:35:53 |
| User entered 'Yes (Y)' | Martha Bunnell-Pollak (b) (4) | 12 Oct 2020 17:14:02 |

US3572330

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:21:46

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User entered 'I' | System | 12 Oct 2020 17:14:02 |

US3572330

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:21:46

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User signature succeeded. | Milton Haber (b) (4) | 21 Mar 2021 00:25:10 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 10 Dec 2020 18:21:35 |
| User entered 'Yes (Y)' | Maria Candelario (b) (4) (b) (4) | 28 Oct 2020 01:39:48 |

US3572330

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:21:46

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

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User signature succeeded. | Milton Haber (b) (4) | 21 Mar 2021 00:25:10 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 10 Dec 2020 18:21:35 |
| User entered '26 Oct 2020' | Maria Candelario (b) (4) (b) (4) | 28 Oct 2020 01:39:48 |

US3572330

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:21:46

[Was visit performed at the participant's home or at the clinic?](#)

| Audit | User | Time (GMT) |
|--------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User signature succeeded. | Milton Haber (b) (4) | 21 Mar 2021 00:25:10 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 10 Dec 2020 18:21:35 |
| User entered 'Clinic (Clinic)' | Maria Candelario (b) (4) | 28 Oct 2020 01:39:48 |
| | (b) (4) | |

US3572330

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:21:46

[Folder OID](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User entered 'VISIT2' | System | 28 Oct 2020 01:39:48 |

US3572330

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:21:46

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User accepted default value 'Pre-Dose (PREDOSE)' | Maria Candelario (b) (4) (b) (4) | 28 Oct 2020 01:42:20 |

US3572330

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:21:46

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User signature succeeded. | Milton Haber (b) (4) | 21 Mar 2021 00:25:10 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 10 Dec 2020 18:23:49 |
| User entered 'Yes (Y)' | Maria Candelario (b) (4) (b) (4) | 28 Oct 2020 01:42:20 |

US3572330

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:21:46

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User signature succeeded. | Milton Haber (b) (4) | 21 Mar 2021 00:25:10 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 10 Dec 2020 18:23:49 |
| User entered '26 Oct 2020' | Maria Candelario (b) (4) (b) (4) | 28 Oct 2020 01:42:20 |

US3572330

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:21:46

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

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User signature succeeded. | Milton Haber (b) (4) | 21 Mar 2021 00:25:10 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 10 Dec 2020 18:23:49 |
| User entered '09:00' | Maria Candelario (b) (4) (b) (4) | 28 Oct 2020 01:42:20 |

US3572330

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:21:46

[Vital Signs Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User entered '26 Oct 2020 09:00' | System | 28 Oct 2020 01:42:20 |

US3572330

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:21:46

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User signature succeeded. | Milton Haber (b) (4) | 21 Mar 2021 00:25:10 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 10 Dec 2020 18:23:49 |
| User entered '97.7' F | Maria Candelario (b) (4) (b) (4) | 28 Oct 2020 01:42:20 |

US3572330

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:21:46

[Route of measurement](#)

| Audit | User | Time (GMT) |
|------------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User signature succeeded. | Milton Haber (b) (4) | 21 Mar 2021 00:25:10 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 10 Dec 2020 18:23:49 |
| User entered 'Other (Other)' | Maria Candelario (b) (4) (b) (4) | 28 Oct 2020 01:42:20 |

US3572330

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:21:46

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User signature succeeded. | Milton Haber (b) (4) | 21 Mar 2021 00:25:10 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 10 Dec 2020 18:23:49 |
| User entered 'temporal' | Maria Candelario (b) (4) | 28 Oct 2020 01:42:20 |
| | (b) (4) | |

US3572330

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:21:46

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User signature succeeded. | Milton Haber (b) (4) | 21 Mar 2021 00:25:10 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 10 Dec 2020 18:23:49 |
| User entered '70' | Maria Candelario (b) (4) (b) (4) | 28 Oct 2020 01:42:20 |

US3572330

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:21:46

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User entered 'bpm' | System | 28 Oct 2020 01:42:20 |

US3572330

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:21:46

[Respiratory Rate \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User signature succeeded. | Milton Haber (b) (4) | 21 Mar 2021 00:25:10 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 10 Dec 2020 18:23:49 |
| User entered '20' | Maria Candelario (b) (4) (b) (4) | 28 Oct 2020 01:42:20 |

US3572330

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:21:46

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User entered 'breaths/min' | System | 28 Oct 2020 01:42:20 |

US3572330

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:21:46

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User signature succeeded. | Milton Haber (b) (4) | 21 Mar 2021 00:25:10 |
| DataPoint Verified. | (b) (4) (u) (4), (b) (6) | 10 Dec 2020 18:23:49 |
| User entered '144' | Maria Candelario (b) (4) (b) (4) | 28 Oct 2020 01:42:20 |

US3572330

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:21:46

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User entered 'mmHg' | System | 28 Oct 2020 01:42:20 |

US3572330

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:21:46

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User signature succeeded. | Milton Haber (b) (4) | 21 Mar 2021 00:25:10 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 10 Dec 2020 18:23:49 |
| User entered '87' | Maria Candelario (b) (4) | 28 Oct 2020 01:42:20 |
| | (b) (4) | |

US3572330

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:21:46

[Diastolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User entered 'mmHg' | System | 28 Oct 2020 01:42:20 |

US3572330

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:21:46

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User accepted default value 'Post-Dose (POSTDOSE)' | Maria Candelario (b) (4) (b) (4) | 28 Oct 2020 01:42:20 |

US3572330

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:21:46

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User signature succeeded. | Milton Haber (b) (4) | 21 Mar 2021 00:25:10 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 10 Dec 2020 18:23:49 |
| User entered 'Yes (Y)' | Maria Candelario (b) (4) (b) (4) | 28 Oct 2020 01:42:20 |

US3572330

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:21:46

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User signature succeeded. | Milton Haber (b) (4) | 21 Mar 2021 00:25:10 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 10 Dec 2020 18:23:49 |
| User entered '26 Oct 2020' | Maria Candelario (b) (4) (b) (4) | 28 Oct 2020 01:42:20 |

US3572330

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:21:46

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

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User signature succeeded. | Milton Haber (b) (4) | 21 Mar 2021 00:25:10 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 10 Dec 2020 18:23:49 |
| User entered '10:08' | Maria Candelario (b) (4) (b) (4) | 28 Oct 2020 01:42:20 |

US3572330

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:21:46

[Vital Signs Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User entered '26 Oct 2020 10:08' | System | 28 Oct 2020 01:42:20 |

US3572330

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:21:46

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User signature succeeded. | Milton Haber (b) (4) | 21 Mar 2021 00:25:10 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 10 Dec 2020 18:23:49 |
| User entered '97.3' F | Maria Candelario (b) (4) (b) (4) | 28 Oct 2020 01:42:20 |

US3572330

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:21:46

[Route of measurement](#)

| Audit | User | Time (GMT) |
|------------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User signature succeeded. | Milton Haber (b) (4) | 21 Mar 2021 00:25:10 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 10 Dec 2020 18:23:49 |
| User entered 'Other (Other)' | Maria Candelario (b) (4) (b) (4) | 28 Oct 2020 01:42:20 |

US3572330

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:21:46

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User signature succeeded. | Milton Haber (b) (4) | 21 Mar 2021 00:25:10 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 10 Dec 2020 18:23:49 |
| User entered 'temporal' | Maria Candelario (b) (4) (b) (4) | 28 Oct 2020 01:42:20 |

US3572330

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:21:46

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User signature succeeded. | Milton Haber (b) (4) | 21 Mar 2021 00:25:10 |
| DataPoint Verified. | (b) (4) (u) (4), (b) (6) | 10 Dec 2020 18:23:49 |
| User entered '72' | Maria Candelario (b) (4) (b) (4) | 28 Oct 2020 01:42:20 |

US3572330

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:21:46

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User entered 'bpm' | System | 28 Oct 2020 01:42:20 |

US3572330

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:21:46

[Respiratory Rate \(xxx\)](#)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 11 Apr 2021 22:12:51 |
| User signature succeeded. | Milton Haber (b) (4) | 21 Mar 2021 00:25:10 |
| User closed query 'Per CDM: As per CCG, respiratory rate is mandatory field. Kindly update.' (Site from DM). | (b) (4) | |
| Query 'Per CDM: As per CCG, respiratory rate is mandatory field. Kindly update.' answered with 'nothing recorded in source for respirations' (Site from DM). | (b) (4), (b) (6) | 07 Jan 2021 08:57:44 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 06 Jan 2021 02:08:05 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4), (b) (6) | 06 Jan 2021 02:07:47 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Dec 2020 18:23:49 |
| User opened query 'Per CDM: As per CCG, respiratory rate is mandatory field. Kindly update.' (Site from DM). | (b) (4), (b) (6) | 29 Oct 2020 08:02:38 |
| User closed query 'Data is required. Please provide.' (Site from System). | (b) (4), (b) (6) | 29 Oct 2020 08:02:01 |
| Query 'Data is required. Please provide.' answered with 'data not collected' (Site from System). | Maria Candelario (b) (4) | 28 Oct 2020 01:42:35 |
| User opened query 'Data is required. Please provide.' (Site from System). | (b) (4) | |
| User entered empty. | System | 28 Oct 2020 01:42:20 |
| | Maria Candelario (b) (4) | 28 Oct 2020 01:42:20 |
| | (b) (4) | |

US3572330

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:21:46

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User entered 'breaths/min' | System | 06 Jan 2021 02:07:47 |
| User entered empty. | System | 28 Oct 2020 01:42:20 |

US3572330

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:21:46

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User signature succeeded. | Milton Haber (b) (4) | 21 Mar 2021 00:25:10 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 10 Dec 2020 18:23:49 |
| User entered '134' | Maria Candelario (b) (4) (b) (4) | 28 Oct 2020 01:42:20 |

US3572330

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:21:46

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User entered 'mmHg' | System | 28 Oct 2020 01:42:20 |

US3572330

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:21:46

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User signature succeeded. | Milton Haber (b) (4) | 21 Mar 2021 00:25:10 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 10 Dec 2020 18:23:49 |
| User entered '89' | Maria Candelario (b) (4) (b) (4) | 28 Oct 2020 01:42:20 |

US3572330

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:21:46

Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User entered 'mmHg' | System | 28 Oct 2020 01:42:20 |

US3572330

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:21:46

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User signature succeeded. | Milton Haber (b) (4) | 21 Mar 2021 00:25:10 |
| DataPoint Verified. | (b) (4) (u) (4), (b) (6) | 10 Dec 2020 18:21:54 |
| User entered 'Yes (Y)' | Maria Candelario (b) (4) (b) (4) | 28 Oct 2020 01:42:53 |

US3572330

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:21:46

Date of examination (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User signature succeeded. | Milton Haber (b) (4) | 21 Mar 2021 00:25:10 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 10 Dec 2020 18:21:54 |
| User entered '26 Oct 2020' | Maria Candelario (b) (4) (b) (4) | 28 Oct 2020 01:42:53 |

US3572330

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:21:46

[Was study treatment given?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User signature succeeded. | Milton Haber (b) (4) | 21 Mar 2021 00:25:10 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 10 Dec 2020 18:22:15 |
| User entered 'Yes (Y)' | Maria Candelario (b) (4) (b) (4) | 26 Oct 2020 15:13:51 |

US3572330

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:21:46

[If No, reason not given](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User signature succeeded. | Milton Haber (b) (4) | 21 Mar 2021 00:25:10 |
| DataPoint Verified. | (b) (4) (u) (4), (b) (6) | 10 Dec 2020 18:22:15 |
| User entered empty. | Maria Candelario (b) (4) (b) (4) | 26 Oct 2020 15:13:51 |

US3572330

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:21:46

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) | 24 Apr 2021 14:40:44 |
| User signature succeeded. | Milton Haber (b) (4) | 21 Mar 2021 00:25:10 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 10 Dec 2020 18:22:15 |
| User entered empty. | Maria Candelario (b) (4) (b) (4) | 26 Oct 2020 15:13:51 |

US3572330

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:21:46

[What was the study treatment?](#)

| Audit | User | Time (GMT) |
|-------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User entered 'MRNA-1273 OR PLACEBO' | System | 26 Oct 2020 15:13:51 |

US3572330

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:21:46

[What was the treatment date? \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User signature succeeded. | Milton Haber (b) (4) | 21 Mar 2021 00:25:10 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 10 Dec 2020 18:22:15 |
| User entered '26 Oct 2020' | Maria Candelario (b) (4) (b) (4) | 26 Oct 2020 15:13:51 |

US3572330

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:21:46

[What was the treatment time? \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User signature succeeded. | Milton Haber (b) (4) | 21 Mar 2021 00:25:10 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 10 Dec 2020 18:22:15 |
| User entered '09:38' | Maria Candelario (b) (4) (b) (4) | 26 Oct 2020 15:13:51 |

US3572330

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:21:46

[Treatment Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User entered '26 Oct 2020 09:38' | System | 26 Oct 2020 15:13:51 |

US3572330

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:21:46

[Which arm was used to give treatment?](#)

| Audit | User | Time (GMT) |
|------------------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User signature succeeded. | Milton Haber (b) (4) | 21 Mar 2021 00:25:10 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 10 Dec 2020 18:22:15 |
| User entered 'Left Arm (LEFT ARM)' | Maria Candelario (b) (4) (b) (4) | 26 Oct 2020 15:13:51 |

US3572330

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:21:46

[What was the frequency of the study treatment dosing?](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Dec 2020 18:22:15 |
| User entered 'ONCE' | System | 26 Oct 2020 15:13:51 |

US3572330

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:21:46

What was the route of administration for the study treatment?

| Audit | User | Time (GMT) |
|------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User entered 'INTRAMUSCULAR' | System | 26 Oct 2020 15:13:51 |

US3572330

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:21:46

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User signature succeeded. | Milton Haber (b) (4) | 21 Mar 2021 00:25:10 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 10 Dec 2020 18:24:02 |
| User entered 'Yes (Y)' | Maria Candelario (b) (4) (b) (4) | 28 Oct 2020 01:43:22 |

US3572330

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:21:46

Collection date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User signature succeeded. | Milton Haber (b) (4) | 21 Mar 2021 00:25:10 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 10 Dec 2020 18:24:02 |
| User entered '26 Oct 2020' | Maria Candelario (b) (4) (b) (4) | 28 Oct 2020 01:43:22 |

US3572330

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:21:46

Collection time (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User signature succeeded. | Milton Haber (b) (4) | 21 Mar 2021 00:25:10 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 10 Dec 2020 18:24:02 |
| User entered '09:13' | Maria Candelario (b) (4) (b) (4) | 28 Oct 2020 01:43:22 |

US3572330

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:21:46

[Collection date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User entered '26 Oct 2020 09:13' | System | 28 Oct 2020 01:43:22 |

US3572330

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 08:21:46

Collection date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User signature succeeded. | Milton Haber (b) (4) | 21 Mar 2021 00:25:10 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 10 Dec 2020 18:24:07 |
| User entered '26 Oct 2020' | Maria Candelario (b) (4) (b) (4) | 28 Oct 2020 01:43:43 |

US3572330

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:21:46

[Lab Test](#)

| Audit | User | Time (GMT) |
|--|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)' | Maria Candelario (b) (4) (b) (4) | 28 Oct 2020 01:43:43 |

US3572330

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:21:46

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User signature succeeded. | Milton Haber (b) (4) | 21 Mar 2021 00:25:10 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 10 Dec 2020 18:24:07 |
| User entered 'Yes (Y)' | Maria Candelario (b) (4) (b) (4) | 28 Oct 2020 01:43:43 |

US3572330

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:21:46

Collection time (00:00 - 23:59)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User signature succeeded. | Milton Haber (b) (4) | 21 Mar 2021 00:25:10 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 10 Dec 2020 18:24:07 |
| User entered '09:08' | Maria Candelario (b) (4) (b) (4) | 28 Oct 2020 01:43:43 |

US3572330

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:21:46

[Collection date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User entered '26 Oct 2020 09:08' | System | 28 Oct 2020 01:43:43 |

US3572330

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:21:46

[Lab Test](#)

| Audit | User | Time (GMT) |
|--|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)' | Maria Candelario (b) (4) (b) (4) | 28 Oct 2020 01:43:43 |

US3572330

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:21:46

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User signature succeeded. | Milton Haber (b) (4) | 21 Mar 2021 00:25:10 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 10 Dec 2020 18:24:07 |
| User entered 'No (N)' | Maria Candelario (b) (4) (b) (4) | 28 Oct 2020 01:43:43 |

US3572330

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:21:46

Collection time (00:00 - 23:59)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User signature succeeded. | Milton Haber (b) (4) | 21 Mar 2021 00:25:10 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 10 Dec 2020 18:24:07 |
| User entered empty. | Maria Candelario (b) (4) (b) (4) | 28 Oct 2020 01:43:43 |

US3572330

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:21:46

[Collection date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User entered empty. | System | 28 Oct 2020 01:43:43 |

US3572330

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:21:46

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User signature succeeded. | Milton Haber (b) (4) | 21 Mar 2021 00:25:10 |
| DataPoint Verified. | (b) (4) (u) (4), (b) (6) | 10 Dec 2020 18:24:18 |
| User entered 'Yes (Y)' | Maria Candelario (b) (4) (b) (4) | 28 Oct 2020 01:43:48 |

US3572330

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:21:46

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User entered 'I' | System | 28 Oct 2020 01:43:48 |

US3572330

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| Data entry locked. | System | 26 Oct 2020 15:13:51 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 26 Oct 2020 15:13:51 |

US3572330

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:21:46

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-10-26T10:14:27', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: '20e8d465-e3f2-4365-a9fd-3ef9bb99dd3d' | System | 26 Oct 2020 15:14:48 |
| User entered 'Yes (Y)' | System | 26 Oct 2020 15:14:48 |

US3572330

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:21:46

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-10-26T10:14:35', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: '20e8d465-e3f2-4365-a9fd-3ef9bb99dd3d' User entered '97.3' | System | 26 Oct 2020 15:14:48 |
| | System | 26 Oct 2020 15:14:48 |

US3572330

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:21:46

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-10-26T10:14:38', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: '20e8d465-e3f2-4365-a9fd-3ef9bb99dd3d' | System | 26 Oct 2020 15:14:48 |
| User entered 'No (N)' | System | 26 Oct 2020 15:14:48 |

US3572330

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:21:46

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-10-26T10:14:43', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: '20e8d465-e3f2-4365-a9fd-3ef9bb99dd3d' | System | 26 Oct 2020 15:14:48 |
| User entered '26 Oct 2020 10:14' | System | 26 Oct 2020 15:14:48 |

US3572330

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:21:46

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| User entered '26 Oct 2020 09:58' | System | 26 Oct 2020 15:13:51 |

US3572330

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:21:46

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| User entered '26 Oct 2020 12:28' | System | 26 Oct 2020 15:13:51 |

US3572330

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| Data entry locked. | System | 26 Oct 2020 15:13:51 |
| User entered 'Day 1, after vaccination (at home)' | System | 26 Oct 2020 15:13:51 |

US3572330

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:21:46

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-10-27T00:12:33', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: 'f69dafb0-39ba-4e8b-bc7a-bd85d5b96e9f' | System | 27 Oct 2020 05:12:49 |
| User entered 'Yes (Y)' | System | 27 Oct 2020 05:12:49 |

US3572330

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:21:46

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-10-27T00:12:39', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: 'f69dafb0-39ba-4e8b-bc7a-bd85d5b96e9f' | System | 27 Oct 2020 05:12:49 |
| User entered '98.6' | System | 27 Oct 2020 05:12:49 |

US3572330

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:21:46

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-10-27T00:12:43', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: 'f69dafb0-39ba-4e8b-bc7a-bd85d5b96e9f' | System | 27 Oct 2020 05:12:49 |
| User entered 'No (N)' | System | 27 Oct 2020 05:12:49 |

US3572330

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:21:46

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-10-27T00:12:47', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: 'f69dafb0-39ba-4e8b-bc7a-bd85d5b96e9f' | System | 27 Oct 2020 05:12:49 |
| User entered '27 Oct 2020 00:12' | System | 27 Oct 2020 05:12:49 |

US3572330

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:21:46

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| User entered '26 Oct 2020 13:23' | System | 26 Oct 2020 15:13:51 |

US3572330

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:21:46

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| User entered '27 Oct 2020 11:59' | System | 26 Oct 2020 15:13:51 |

US3572330

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| Data entry locked. | System | 26 Oct 2020 15:13:51 |
| User entered 'Day 2' | System | 26 Oct 2020 15:13:51 |

US3572330

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:21:46

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-10-27T23:27:33', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: '5c2279e2-128f-4b8b-940c-62d7a1eb449f' | System | 28 Oct 2020 04:27:52 |
| User entered 'Yes (Y)' | System | 28 Oct 2020 04:27:52 |

US3572330

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:21:46

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-10-27T23:27:40', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: '5c2279e2-128f-4b8b-940c-62d7a1eb449f' | System | 28 Oct 2020 04:27:52 |
| User entered '98.6' | System | 28 Oct 2020 04:27:52 |

US3572330

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:21:46

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-10-27T23:27:43', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: '5c2279e2-128f-4b8b-940c-62d7a1eb449f' | System | 28 Oct 2020 04:27:52 |
| User entered 'No (N)' | System | 28 Oct 2020 04:27:52 |

US3572330

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:21:46

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-10-27T23:27:48', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: '5c2279e2-128f-4b8b-940c-62d7a1eb449f' | System | 28 Oct 2020 04:27:52 |
| User entered '27 Oct 2020 23:27' | System | 28 Oct 2020 04:27:52 |

US3572330

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:21:46

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| User entered '27 Oct 2020 12:00' | System | 26 Oct 2020 15:13:51 |

US3572330

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:21:46

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| User entered '28 Oct 2020 11:59' | System | 26 Oct 2020 15:13:51 |

US3572330

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| Data entry locked. | System | 26 Oct 2020 15:13:51 |
| User entered 'Day 3' | System | 26 Oct 2020 15:13:51 |

US3572330

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:21:46

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-10-29T11:51:24', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: 'd68ac320-7aa0-49c9-9307-f79a3c7a53fb' | System | 29 Oct 2020 16:51:57 |
| User entered 'Yes (Y)' | System | 29 Oct 2020 16:51:57 |

US3572330

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:21:46

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-10-29T11:51:32', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: 'd68ac320-7aa0-49c9-9307-f79a3c7a53fb' User entered '97.0' | System | 29 Oct 2020 16:51:57 |
| | System | 29 Oct 2020 16:51:57 |

US3572330

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:21:46

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-10-29T11:51:37', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: 'd68ac320-7aa0-49c9-9307-f79a3c7a53fb' | System | 29 Oct 2020 16:51:57 |
| User entered 'No (N)' | System | 29 Oct 2020 16:51:57 |

US3572330

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:21:46

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-10-29T11:51:50', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: 'd68ac320-7aa0-49c9-9307-f79a3c7a53fb' | System | 29 Oct 2020 16:51:57 |
| User entered '29 Oct 2020 11:51' | System | 29 Oct 2020 16:51:57 |

US3572330

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:21:46

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| User entered '28 Oct 2020 12:00' | System | 26 Oct 2020 15:13:51 |

US3572330

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:21:46

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| User entered '29 Oct 2020 11:59' | System | 26 Oct 2020 15:13:51 |

US3572330

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| Data entry locked. | System | 26 Oct 2020 15:13:51 |
| User entered 'Day 4' | System | 26 Oct 2020 15:13:51 |

US3572330

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:21:46

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-10-29T22:26:40', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: '0570a909-e300-4369-8afa-9d60d3f39fcc' | System | 30 Oct 2020 03:27:02 |
| User entered 'Yes (Y)' | System | 30 Oct 2020 03:27:02 |

US3572330

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:21:46

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-10-29T22:26:47', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: '0570a909-e300-4369-8afa-9d60d3f39fcc' | System | 30 Oct 2020 03:27:02 |
| User entered '97.5' | System | 30 Oct 2020 03:27:02 |

US3572330

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:21:46

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-10-29T22:26:50', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: '0570a909-e300-4369-8afa-9d60d3f39fcc' | System | 30 Oct 2020 03:27:02 |
| User entered 'No (N)' | System | 30 Oct 2020 03:27:02 |

US3572330

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:21:46

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-10-29T22:26:56', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: '0570a909-e300-4369-8afa-9d60d3f39fcc' | System | 30 Oct 2020 03:27:02 |
| User entered '29 Oct 2020 22:26' | System | 30 Oct 2020 03:27:02 |

US3572330

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:21:46

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| User entered '29 Oct 2020 12:00' | System | 26 Oct 2020 15:13:51 |

US3572330

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:21:46

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| User entered '30 Oct 2020 11:59' | System | 26 Oct 2020 15:13:51 |

US3572330

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| Data entry locked. | System | 26 Oct 2020 15:13:51 |
| User entered 'Day 5' | System | 26 Oct 2020 15:13:51 |

US3572330

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:21:46

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-10-30T22:10:11', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: 'c5e77e8f-5089-4912-b7b5-682206c4ace9' | System | 31 Oct 2020 03:10:23 |
| User entered 'Yes (Y)' | System | 31 Oct 2020 03:10:23 |

US3572330

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:21:46

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-10-30T22:10:16', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: 'c5e77e8f-5089-4912-b7b5-682206c4ace9' | System | 31 Oct 2020 03:10:23 |
| User entered '97.0' | System | 31 Oct 2020 03:10:23 |

US3572330

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:21:46

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-10-30T22:10:18', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: 'c5e77e8f-5089-4912-b7b5-682206c4ace9' | System | 31 Oct 2020 03:10:23 |
| User entered 'No (N)' | System | 31 Oct 2020 03:10:23 |

US3572330

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:21:46

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-10-30T22:10:20', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: 'c5e77e8f-5089-4912-b7b5-682206c4ace9' | System | 31 Oct 2020 03:10:23 |
| User entered '30 Oct 2020 22:10' | System | 31 Oct 2020 03:10:23 |

US3572330

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:21:46

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| User entered '30 Oct 2020 12:00' | System | 26 Oct 2020 15:13:51 |

US3572330

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:21:46

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| User entered '31 Oct 2020 11:59' | System | 26 Oct 2020 15:13:51 |

US3572330

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| Data entry locked. | System | 26 Oct 2020 15:13:51 |
| User entered 'Day 6' | System | 26 Oct 2020 15:13:51 |

US3572330

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:21:46

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |

US3572330

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:21:46

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |

US3572330

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:21:46

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

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |

US3572330

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:21:46

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

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |

US3572330

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:21:46

To **PREVENT** pain or fever from occurring

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |

US3572330

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:21:46

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |

US3572330

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:21:46

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| User entered '31 Oct 2020 12:00' | System | 26 Oct 2020 15:13:51 |

US3572330

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:21:46

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| User entered '01 Nov 2020 11:59' | System | 26 Oct 2020 15:13:51 |

US3572330

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| Data entry locked. | System | 26 Oct 2020 15:13:51 |
| User entered 'Day 7' | System | 26 Oct 2020 15:13:51 |

US3572330

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:21:46

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |

US3572330

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:21:46

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |

US3572330

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:21:46

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

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |

US3572330

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:21:46

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

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |

US3572330

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:21:46

To **PREVENT** pain or fever from occurring

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |

US3572330

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:21:46

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |

US3572330

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:21:46

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| User entered '01 Nov 2020 12:00' | System | 26 Oct 2020 15:13:51 |

US3572330

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:21:46

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| User entered '02 Nov 2020 11:59' | System | 26 Oct 2020 15:13:51 |

US3572330

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| Data entry locked. | System | 26 Oct 2020 15:13:51 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 26 Oct 2020 15:13:51 |

US3572330

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:21:46

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-10-26T10:14:48', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: 'c49abb59-9e67-422a-ac8d-5e3a72f7ed11' | System | 26 Oct 2020 15:15:06 |
| User entered 'Does not interfere with activity (2)' | System | 26 Oct 2020 15:15:06 |

US3572330

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:21:46

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-10-26T10:14:51', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: 'c49abb59-9e67-422a-ac8d-5e3a72f7ed11' | System | 26 Oct 2020 15:15:06 |
| User entered 'No (N)' | System | 26 Oct 2020 15:15:06 |

US3572330

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:21:46

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-10-26T10:14:54', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: 'c49abb59-9e67-422a-ac8d-5e3a72f7ed11' | System | 26 Oct 2020 15:15:06 |
| User entered 'No (N)' | System | 26 Oct 2020 15:15:06 |

US3572330

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:21:46

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-10-26T10:14:57', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: 'c49abb59-9e67-422a-ac8d-5e3a72f7ed11' | System | 26 Oct 2020 15:15:06 |
| User entered 'None (1)' | System | 26 Oct 2020 15:15:06 |

US3572330

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:21:46

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-10-26T10:14:59', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: 'c49abb59-9e67-422a-ac8d-5e3a72f7ed11' | System | 26 Oct 2020 15:15:06 |
| User entered '26 Oct 2020 10:14' | System | 26 Oct 2020 15:15:06 |

US3572330

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:21:46

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| User entered '26 Oct 2020 09:58' | System | 26 Oct 2020 15:13:51 |

US3572330

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:21:46

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| User entered '26 Oct 2020 12:28' | System | 26 Oct 2020 15:13:51 |

US3572330

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| Data entry locked. | System | 26 Oct 2020 15:13:51 |
| User entered 'Day 1, after vaccination (at home)' | System | 26 Oct 2020 15:13:51 |

US3572330

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:21:46

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-10-26T20:16:53', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: '4d411706-a7a8-458a-98b5-13559513b235' | System | 27 Oct 2020 01:17:29 |
| User entered 'Does not interfere with activity (2)' | System | 27 Oct 2020 01:17:29 |

US3572330

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:21:46

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-10-26T20:17:15', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: '4d411706-a7a8-458a-98b5-13559513b235' | System | 27 Oct 2020 01:17:29 |
| User entered 'No (N)' | System | 27 Oct 2020 01:17:29 |

US3572330

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:21:46

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-10-26T20:17:18', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: '4d411706-a7a8-458a-98b5-13559513b235' | System | 27 Oct 2020 01:17:29 |
| User entered 'No (N)' | System | 27 Oct 2020 01:17:29 |

US3572330

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:21:46

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-10-26T20:17:22', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: '4d411706-a7a8-458a-98b5-13559513b235' | System | 27 Oct 2020 01:17:29 |
| User entered 'None (1)' | System | 27 Oct 2020 01:17:29 |

US3572330

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:21:46

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-10-26T20:17:24', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: '4d411706-a7a8-458a-98b5-13559513b235' User entered '26 Oct 2020 20:17' | System | 27 Oct 2020 01:17:29 |
| | System | 27 Oct 2020 01:17:29 |

US3572330

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:21:46

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| User entered '26 Oct 2020 13:23' | System | 26 Oct 2020 15:13:51 |

US3572330

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:21:46

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| User entered '27 Oct 2020 11:59' | System | 26 Oct 2020 15:13:51 |

US3572330

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| Data entry locked. | System | 26 Oct 2020 15:13:51 |
| User entered 'Day 2' | System | 26 Oct 2020 15:13:51 |

US3572330

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:21:46

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-10-27T23:27:55', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: '517c762c-69b5-43f5-814a-a0015479ce87' | System | 28 Oct 2020 04:28:17 |
| User entered 'Does not interfere with activity (2)' | System | 28 Oct 2020 04:28:17 |

US3572330

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:21:46

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-10-27T23:28:02', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: '517c762c-69b5-43f5-814a-a0015479ce87' | System | 28 Oct 2020 04:28:17 |
| User entered 'No (N)' | System | 28 Oct 2020 04:28:17 |

US3572330

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:21:46

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-10-27T23:28:05', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: '517c762c-69b5-43f5-814a-a0015479ce87' | System | 28 Oct 2020 04:28:17 |
| User entered 'No (N)' | System | 28 Oct 2020 04:28:17 |

US3572330

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:21:46

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-10-27T23:28:09', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: '517c762c-69b5-43f5-814a-a0015479ce87' | System | 28 Oct 2020 04:28:17 |
| User entered 'None (1)' | System | 28 Oct 2020 04:28:17 |

US3572330

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:21:46

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-10-27T23:28:11', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: '517c762c-69b5-43f5-814a-a0015479ce87' | System | 28 Oct 2020 04:28:17 |
| User entered '27 Oct 2020 23:28' | System | 28 Oct 2020 04:28:17 |

US3572330

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:21:46

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| User entered '27 Oct 2020 12:00' | System | 26 Oct 2020 15:13:51 |

US3572330

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:21:46

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| User entered '28 Oct 2020 11:59' | System | 26 Oct 2020 15:13:51 |

US3572330

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| Data entry locked. | System | 26 Oct 2020 15:13:51 |
| User entered 'Day 3' | System | 26 Oct 2020 15:13:51 |

US3572330

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:21:46

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-10-29T11:51:56', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: 'b51c2ec4-d45d-477f-ac45-d8a937ddec74' | System | 29 Oct 2020 16:52:10 |
| User entered 'Does not interfere with activity (2)' | System | 29 Oct 2020 16:52:10 |

US3572330

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:21:46

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-10-29T11:51:59', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: 'b51c2ec4-d45d-477f-ac45-d8a937ddec74' | System | 29 Oct 2020 16:52:10 |
| User entered 'No (N)' | System | 29 Oct 2020 16:52:10 |

US3572330

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:21:46

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-10-29T11:52:02', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: 'b51c2ec4-d45d-477f-ac45-d8a937ddec74' | System | 29 Oct 2020 16:52:10 |
| User entered 'No (N)' | System | 29 Oct 2020 16:52:10 |

US3572330

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:21:46

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-10-29T11:52:04', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: 'b51c2ec4-d45d-477f-ac45-d8a937ddec74' | System | 29 Oct 2020 16:52:10 |
| User entered 'None (1)' | System | 29 Oct 2020 16:52:10 |

US3572330

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:21:46

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-10-29T11:52:06', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: 'b51c2ec4-d45d-477f-ac45-d8a937ddec74' | System | 29 Oct 2020 16:52:10 |
| User entered '29 Oct 2020 11:52' | System | 29 Oct 2020 16:52:10 |

US3572330

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:21:46

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| User entered '28 Oct 2020 12:00' | System | 26 Oct 2020 15:13:51 |

US3572330

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:21:46

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| User entered '29 Oct 2020 11:59' | System | 26 Oct 2020 15:13:51 |

US3572330

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| Data entry locked. | System | 26 Oct 2020 15:13:51 |
| User entered 'Day 4' | System | 26 Oct 2020 15:13:51 |

US3572330

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:21:46

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-10-29T22:27:09', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: 'da001c42-d637-4919-a14e-a5c3e29ba278' | System | 30 Oct 2020 03:27:31 |
| User entered 'None (1)' | System | 30 Oct 2020 03:27:31 |

US3572330

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:21:46

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-10-29T22:27:15', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: 'da001c42-d637-4919-a14e-a5c3e29ba278' | System | 30 Oct 2020 03:27:31 |
| User entered 'No (N)' | System | 30 Oct 2020 03:27:31 |

US3572330

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:21:46

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-10-29T22:27:17', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: 'da001c42-d637-4919-a14e-a5c3e29ba278' | System | 30 Oct 2020 03:27:31 |
| User entered 'No (N)' | System | 30 Oct 2020 03:27:31 |

US3572330

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:21:46

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-10-29T22:27:22', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: 'da001c42-d637-4919-a14e-a5c3e29ba278' | System | 30 Oct 2020 03:27:31 |
| User entered 'None (1)' | System | 30 Oct 2020 03:27:31 |

US3572330

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:21:46

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-10-29T22:27:28', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: 'da001c42-d637-4919-a14e-a5c3e29ba278' | System | 30 Oct 2020 03:27:31 |
| User entered '29 Oct 2020 22:27' | System | 30 Oct 2020 03:27:31 |

US3572330

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:21:46

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| User entered '29 Oct 2020 12:00' | System | 26 Oct 2020 15:13:51 |

US3572330

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:21:46

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| User entered '30 Oct 2020 11:59' | System | 26 Oct 2020 15:13:51 |

US3572330

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| Data entry locked. | System | 26 Oct 2020 15:13:51 |
| User entered 'Day 5' | System | 26 Oct 2020 15:13:51 |

US3572330

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:21:46

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-10-30T22:09:34', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: '83284524-c4ee-4dc7-b496-ac047f1a0cf8' | System | 31 Oct 2020 03:10:02 |
| User entered 'None (1)' | System | 31 Oct 2020 03:10:02 |

US3572330

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:21:46

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-10-30T22:09:36', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: '83284524-c4ee-4dc7-b496-ac047f1a0cf8' | System | 31 Oct 2020 03:10:02 |
| User entered 'No (N)' | System | 31 Oct 2020 03:10:02 |

US3572330

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:21:46

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-10-30T22:09:38', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: '83284524-c4ee-4dc7-b496-ac047f1a0cf8' | System | 31 Oct 2020 03:10:02 |
| User entered 'No (N)' | System | 31 Oct 2020 03:10:02 |

US3572330

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:21:46

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-10-30T22:09:40', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: '83284524-c4ee-4dc7-b496-ac047f1a0cf8' | System | 31 Oct 2020 03:10:02 |
| User entered 'None (1)' | System | 31 Oct 2020 03:10:02 |

US3572330

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:21:46

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-10-30T22:09:58', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: '83284524-c4ee-4dc7-b496-ac047f1a0cf8' | System | 31 Oct 2020 03:10:02 |
| User entered '30 Oct 2020 22:09' | System | 31 Oct 2020 03:10:02 |

US3572330

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:21:46

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| User entered '30 Oct 2020 12:00' | System | 26 Oct 2020 15:13:51 |

US3572330

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:21:46

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| User entered '31 Oct 2020 11:59' | System | 26 Oct 2020 15:13:51 |

US3572330

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| Data entry locked. | System | 26 Oct 2020 15:13:51 |
| User entered 'Day 6' | System | 26 Oct 2020 15:13:51 |

US3572330

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:21:46

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

Please select one response below

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |

US3572330

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:21:46

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |

US3572330

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:21:46

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

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

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |

US3572330

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:21:46

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

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |

US3572330

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:21:46

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

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

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |

US3572330

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:21:46

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

Please select one response below

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |

US3572330

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:21:46

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |

US3572330

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:21:46

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| User entered '31 Oct 2020 12:00' | System | 26 Oct 2020 15:13:51 |

US3572330

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:21:46

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| User entered '01 Nov 2020 11:59' | System | 26 Oct 2020 15:13:51 |

US3572330

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| Data entry locked. | System | 26 Oct 2020 15:13:51 |
| User entered 'Day 7' | System | 26 Oct 2020 15:13:51 |

US3572330

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:21:46

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

Please select one response below

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |

US3572330

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:21:46

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |

US3572330

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:21:46

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

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

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |

US3572330

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:21:46

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

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |

US3572330

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:21:46

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

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

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |

US3572330

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:21:46

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

Please select one response below

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |

US3572330

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:21:46

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |

US3572330

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:21:46

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| User entered '01 Nov 2020 12:00' | System | 26 Oct 2020 15:13:51 |

US3572330

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:21:46

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| User entered '02 Nov 2020 11:59' | System | 26 Oct 2020 15:13:51 |

US3572330

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| Data entry locked. | System | 26 Oct 2020 15:13:51 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 26 Oct 2020 15:13:51 |

US3572330

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:21:46

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-10-26T10:15:03', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: '62aa857b-ace6-4311-a0c4-9d30be0e18f3' | System | 26 Oct 2020 15:15:20 |
| User entered 'None (0)' | System | 26 Oct 2020 15:15:20 |

US3572330

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:21:46

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-10-26T10:15:05', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: '62aa857b-ace6-4311-a0c4-9d30be0e18f3' | System | 26 Oct 2020 15:15:20 |
| User entered 'None (0)' | System | 26 Oct 2020 15:15:20 |

US3572330

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:21:46

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-10-26T10:15:07', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: '62aa857b-ace6-4311-a0c4-9d30be0e18f3' | System | 26 Oct 2020 15:15:20 |
| User entered 'None (0)' | System | 26 Oct 2020 15:15:20 |

US3572330

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:21:46

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-10-26T10:15:09', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: '62aa857b-ace6-4311-a0c4-9d30be0e18f3' | System | 26 Oct 2020 15:15:20 |
| User entered 'None (0)' | System | 26 Oct 2020 15:15:20 |

US3572330

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:21:46

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-10-26T10:15:11', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: '62aa857b-ace6-4311-a0c4-9d30be0e18f3' | System | 26 Oct 2020 15:15:20 |
| User entered 'None (0)' | System | 26 Oct 2020 15:15:20 |

US3572330

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:21:46

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-10-26T10:15:12', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: '62aa857b-ace6-4311-a0c4-9d30be0e18f3' | System | 26 Oct 2020 15:15:20 |
| User entered 'None (0)' | System | 26 Oct 2020 15:15:20 |

US3572330

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:21:46

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-10-26T10:15:14', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: '62aa857b-ace6-4311-a0c4-9d30be0e18f3' | System | 26 Oct 2020 15:15:20 |
| User entered 'No (N)' | System | 26 Oct 2020 15:15:20 |

US3572330

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:21:46

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-10-26T10:15:16', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: '62aa857b-ace6-4311-a0c4-9d30be0e18f3' | System | 26 Oct 2020 15:15:20 |
| User entered '26 Oct 2020 10:15' | System | 26 Oct 2020 15:15:20 |

US3572330

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:21:46

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| User entered '26 Oct 2020 09:58' | System | 26 Oct 2020 15:13:51 |

US3572330

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:21:46

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| User entered '26 Oct 2020 12:28' | System | 26 Oct 2020 15:13:51 |

US3572330

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| Data entry locked. | System | 26 Oct 2020 15:13:51 |
| User entered 'Day 1, after vaccination (at home)' | System | 26 Oct 2020 15:13:51 |

US3572330

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:21:46

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-10-26T20:17:29', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: 'c30c3ae5-713f-4ff6-b36e-7c29248eac75' | System | 27 Oct 2020 01:17:57 |
| User entered 'No interference with activity (1)' | System | 27 Oct 2020 01:17:57 |

US3572330

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:21:46

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-10-26T20:17:35', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: 'c30c3ae5-713f-4ff6-b36e-7c29248eac75' | System | 27 Oct 2020 01:17:57 |
| User entered 'No interference with activity (1)' | System | 27 Oct 2020 01:17:57 |

US3572330

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:21:46

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-10-26T20:17:39', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: 'c30c3ae5-713f-4ff6-b36e-7c29248eac75' | System | 27 Oct 2020 01:17:57 |
| User entered 'None (0)' | System | 27 Oct 2020 01:17:57 |

US3572330

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:21:46

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-10-26T20:17:42', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: 'c30c3ae5-713f-4ff6-b36e-7c29248eac75' | System | 27 Oct 2020 01:17:57 |
| User entered 'None (0)' | System | 27 Oct 2020 01:17:57 |

US3572330

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:21:46

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-10-26T20:17:44', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: 'c30c3ae5-713f-4ff6-b36e-7c29248eac75' | System | 27 Oct 2020 01:17:57 |
| User entered 'None (0)' | System | 27 Oct 2020 01:17:57 |

US3572330

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:21:46

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-10-26T20:17:47', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: 'c30c3ae5-713f-4ff6-b36e-7c29248eac75' | System | 27 Oct 2020 01:17:57 |
| User entered 'None (0)' | System | 27 Oct 2020 01:17:57 |

US3572330

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:21:46

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-10-26T20:17:50', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: 'c30c3ae5-713f-4ff6-b36e-7c29248eac75' | System | 27 Oct 2020 01:17:57 |
| User entered 'No (N)' | System | 27 Oct 2020 01:17:57 |

US3572330

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:21:46

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-10-26T20:17:53', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: 'c30c3ae5-713f-4ff6-b36e-7c29248eac75' | System | 27 Oct 2020 01:17:57 |
| User entered '26 Oct 2020 20:17' | System | 27 Oct 2020 01:17:57 |

US3572330

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:21:46

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| User entered '26 Oct 2020 13:23' | System | 26 Oct 2020 15:13:51 |

US3572330

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:21:46

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| User entered '27 Oct 2020 11:59' | System | 26 Oct 2020 15:13:51 |

US3572330

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| Data entry locked. | System | 26 Oct 2020 15:13:51 |
| User entered 'Day 2' | System | 26 Oct 2020 15:13:51 |

US3572330

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:21:46

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-10-27T23:28:17', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: 'f1d009c8-e9d5-4ebd-a89c-10441f91ea04' | System | 28 Oct 2020 04:28:46 |
| User entered 'No interference with activity (1)' | System | 28 Oct 2020 04:28:46 |

US3572330

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:21:46

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-10-27T23:28:20', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: 'f1d009c8-e9d5-4ebd-a89c-10441f91ea04' | System | 28 Oct 2020 04:28:46 |
| User entered 'No interference with activity (1)' | System | 28 Oct 2020 04:28:46 |

US3572330

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:21:46

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-10-27T23:28:24', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: 'f1d009c8-e9d5-4ebd-a89c-10441f91ea04' | System | 28 Oct 2020 04:28:46 |
| User entered 'No interference with activity (1)' | System | 28 Oct 2020 04:28:46 |

US3572330

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:21:46

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-10-27T23:28:28', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: 'f1d009c8-e9d5-4ebd-a89c-10441f91ea04' | System | 28 Oct 2020 04:28:46 |
| User entered 'None (0)' | System | 28 Oct 2020 04:28:46 |

US3572330

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:21:46

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-10-27T23:28:31', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: 'f1d009c8-e9d5-4ebd-a89c-10441f91ea04' | System | 28 Oct 2020 04:28:46 |
| User entered 'None (0)' | System | 28 Oct 2020 04:28:46 |

US3572330

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:21:46

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-10-27T23:28:34', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: 'f1d009c8-e9d5-4ebd-a89c-10441f91ea04' | System | 28 Oct 2020 04:28:46 |
| User entered 'None (0)' | System | 28 Oct 2020 04:28:46 |

US3572330

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:21:46

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-10-27T23:28:39', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: 'f1d009c8-e9d5-4ebd-a89c-10441f91ea04' | System | 28 Oct 2020 04:28:46 |
| User entered 'No (N)' | System | 28 Oct 2020 04:28:46 |

US3572330

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:21:46

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-10-27T23:28:42', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: 'f1d009c8-e9d5-4ebd-a89c-10441f91ea04' | System | 28 Oct 2020 04:28:46 |
| User entered '27 Oct 2020 23:28' | System | 28 Oct 2020 04:28:46 |

US3572330

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:21:46

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| User entered '27 Oct 2020 12:00' | System | 26 Oct 2020 15:13:51 |

US3572330

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:21:46

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| User entered '28 Oct 2020 11:59' | System | 26 Oct 2020 15:13:51 |

US3572330

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| Data entry locked. | System | 26 Oct 2020 15:13:51 |
| User entered 'Day 3' | System | 26 Oct 2020 15:13:51 |

US3572330

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:21:46

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-10-29T11:52:11', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: '273ec0ba-4cfe-4a45-a558-2247302df91a' | System | 29 Oct 2020 16:52:31 |
| User entered 'No interference with activity (1)' | System | 29 Oct 2020 16:52:31 |

US3572330

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:21:46

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-10-29T11:52:14', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: '273ec0ba-4cfe-4a45-a558-2247302df91a' | System | 29 Oct 2020 16:52:31 |
| User entered 'None (0)' | System | 29 Oct 2020 16:52:31 |

US3572330

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:21:46

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-10-29T11:52:16', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: '273ec0ba-4cfe-4a45-a558-2247302df91a' | System | 29 Oct 2020 16:52:31 |
| User entered 'None (0)' | System | 29 Oct 2020 16:52:31 |

US3572330

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:21:46

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-10-29T11:52:19', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: '273ec0ba-4cfe-4a45-a558-2247302df91a' | System | 29 Oct 2020 16:52:31 |
| User entered 'None (0)' | System | 29 Oct 2020 16:52:31 |

US3572330

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:21:46

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-10-29T11:52:21', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: '273ec0ba-4cfe-4a45-a558-2247302df91a' | System | 29 Oct 2020 16:52:31 |
| User entered 'None (0)' | System | 29 Oct 2020 16:52:31 |

US3572330

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:21:46

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-10-29T11:52:22', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: '273ec0ba-4cfe-4a45-a558-2247302df91a' | System | 29 Oct 2020 16:52:31 |
| User entered 'None (0)' | System | 29 Oct 2020 16:52:31 |

US3572330

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:21:46

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-10-29T11:52:24', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: '273ec0ba-4cfe-4a45-a558-2247302df91a' | System | 29 Oct 2020 16:52:31 |
| User entered 'No (N)' | System | 29 Oct 2020 16:52:31 |

US3572330

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:21:46

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-10-29T11:52:27', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: '273ec0ba-4cfe-4a45-a558-2247302df91a' | System | 29 Oct 2020 16:52:31 |
| User entered '29 Oct 2020 11:52' | System | 29 Oct 2020 16:52:31 |

US3572330

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:21:46

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| User entered '28 Oct 2020 12:00' | System | 26 Oct 2020 15:13:51 |

US3572330

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:21:46

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| User entered '29 Oct 2020 11:59' | System | 26 Oct 2020 15:13:51 |

US3572330

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| Data entry locked. | System | 26 Oct 2020 15:13:51 |
| User entered 'Day 4' | System | 26 Oct 2020 15:13:51 |

US3572330

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:21:46

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-10-29T22:27:37', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: 'd71bc655-d7e5-44e7-8509-8d8f3c10ff7a' | System | 30 Oct 2020 03:28:03 |
| User entered 'No interference with activity (1)' | System | 30 Oct 2020 03:28:03 |

US3572330

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:21:46

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-10-29T22:27:39', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: 'd71bc655-d7e5-44e7-8509-8d8f3c10ff7a' | System | 30 Oct 2020 03:28:03 |
| User entered 'None (0)' | System | 30 Oct 2020 03:28:03 |

US3572330

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:21:46

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-10-29T22:27:40', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: 'd71bc655-d7e5-44e7-8509-8d8f3c10ff7a' | System | 30 Oct 2020 03:28:03 |
| User entered 'None (0)' | System | 30 Oct 2020 03:28:03 |

US3572330

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:21:46

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-10-29T22:27:42', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: 'd71bc655-d7e5-44e7-8509-8d8f3c10ff7a' | System | 30 Oct 2020 03:28:03 |
| User entered 'None (0)' | System | 30 Oct 2020 03:28:03 |

US3572330

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:21:46

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-10-29T22:27:46', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: 'd71bc655-d7e5-44e7-8509-8d8f3c10ff7a' | System | 30 Oct 2020 03:28:03 |
| User entered 'None (0)' | System | 30 Oct 2020 03:28:03 |

US3572330

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:21:46

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-10-29T22:27:48', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: 'd71bc655-d7e5-44e7-8509-8d8f3c10ff7a' | System | 30 Oct 2020 03:28:03 |
| User entered 'None (0)' | System | 30 Oct 2020 03:28:03 |

US3572330

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:21:46

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-10-29T22:27:52', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: 'd71bc655-d7e5-44e7-8509-8d8f3c10ff7a' | System | 30 Oct 2020 03:28:03 |
| User entered 'No (N)' | System | 30 Oct 2020 03:28:03 |

US3572330

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:21:46

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-10-29T22:27:56', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: 'd71bc655-d7e5-44e7-8509-8d8f3c10ff7a' | System | 30 Oct 2020 03:28:03 |
| User entered '29 Oct 2020 22:27' | System | 30 Oct 2020 03:28:03 |

US3572330

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:21:46

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| User entered '29 Oct 2020 12:00' | System | 26 Oct 2020 15:13:51 |

US3572330

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:21:46

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| User entered '30 Oct 2020 11:59' | System | 26 Oct 2020 15:13:51 |

US3572330

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| Data entry locked. | System | 26 Oct 2020 15:13:51 |
| User entered 'Day 5' | System | 26 Oct 2020 15:13:51 |

US3572330

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:21:46

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-10-30T22:09:16', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: 'b3f76339-90ef-4b91-8c2c-d53c2b14bfa6' | System | 31 Oct 2020 03:09:34 |
| User entered 'None (0)' | System | 31 Oct 2020 03:09:34 |

US3572330

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:21:46

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-10-30T22:09:17', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: 'b3f76339-90ef-4b91-8c2c-d53c2b14bfa6' | System | 31 Oct 2020 03:09:34 |
| User entered 'None (0)' | System | 31 Oct 2020 03:09:34 |

US3572330

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:21:46

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-10-30T22:09:19', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: 'b3f76339-90ef-4b91-8c2c-d53c2b14bfa6' | System | 31 Oct 2020 03:09:34 |
| User entered 'None (0)' | System | 31 Oct 2020 03:09:34 |

US3572330

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:21:46

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-10-30T22:09:20', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: 'b3f76339-90ef-4b91-8c2c-d53c2b14bfa6' | System | 31 Oct 2020 03:09:34 |
| User entered 'None (0)' | System | 31 Oct 2020 03:09:34 |

US3572330

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:21:46

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-10-30T22:09:22', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: 'b3f76339-90ef-4b91-8c2c-d53c2b14bfa6' | System | 31 Oct 2020 03:09:34 |
| User entered 'None (0)' | System | 31 Oct 2020 03:09:34 |

US3572330

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:21:46

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-10-30T22:09:23', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: 'b3f76339-90ef-4b91-8c2c-d53c2b14bfa6' | System | 31 Oct 2020 03:09:34 |
| User entered 'None (0)' | System | 31 Oct 2020 03:09:34 |

US3572330

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:21:46

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-10-30T22:09:25', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: 'b3f76339-90ef-4b91-8c2c-d53c2b14bfa6' | System | 31 Oct 2020 03:09:34 |
| User entered 'No (N)' | System | 31 Oct 2020 03:09:34 |

US3572330

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:21:46

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-10-30T22:09:30', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: 'b3f76339-90ef-4b91-8c2c-d53c2b14bfa6' | System | 31 Oct 2020 03:09:34 |
| User entered '30 Oct 2020 22:09' | System | 31 Oct 2020 03:09:34 |

US3572330

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:21:46

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| User entered '30 Oct 2020 12:00' | System | 26 Oct 2020 15:13:51 |

US3572330

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:21:46

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| User entered '31 Oct 2020 11:59' | System | 26 Oct 2020 15:13:51 |

US3572330

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| Data entry locked. | System | 26 Oct 2020 15:13:51 |
| User entered 'Day 6' | System | 26 Oct 2020 15:13:51 |

US3572330

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:21:46

HEADACHE

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |

US3572330

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:21:46

FATIGUE

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |

US3572330

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:21:46

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |

US3572330

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:21:46

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |

US3572330

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:21:46

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |

US3572330

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:21:46

CHILLS

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |

US3572330

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:21:46

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

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |

US3572330

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:21:46

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |

US3572330

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:21:46

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| User entered '31 Oct 2020 12:00' | System | 26 Oct 2020 15:13:51 |

US3572330

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:21:46

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| User entered '01 Nov 2020 11:59' | System | 26 Oct 2020 15:13:51 |

US3572330

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| Data entry locked. | System | 26 Oct 2020 15:13:51 |
| User entered 'Day 7' | System | 26 Oct 2020 15:13:51 |

US3572330

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:21:46

HEADACHE

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |

US3572330

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:21:46

FATIGUE

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |

US3572330

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:21:46

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |

US3572330

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:21:46

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |

US3572330

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:21:46

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |

US3572330

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:21:46

CHILLS

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |

US3572330

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:21:46

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

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |

US3572330

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:21:46

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |

US3572330

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:21:46

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| User entered '01 Nov 2020 12:00' | System | 26 Oct 2020 15:13:51 |

US3572330

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:21:46

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:24:18 |
| User entered '02 Nov 2020 11:59' | System | 26 Oct 2020 15:13:51 |

US3572330

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:21:46

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User signature succeeded. | Milton Haber (b) (4) | 21 Mar 2021 00:25:10 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 10 Dec 2020 20:36:10 |
| User entered 'Yes (Y)' | Martha Bunnell-Pollak (b) (4) | 02 Nov 2020 16:07:34 |

US3572330

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:21:46

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

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User signature succeeded. | Milton Haber (b) (4) | 21 Mar 2021 00:25:10 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 10 Dec 2020 20:36:10 |
| User entered '2 Nov 2020' | Martha Bunnell-Pollak (b) (4) | 02 Nov 2020 16:07:34 |

US3572330

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:21:46

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User signature succeeded. | Milton Haber (b) (4) | 21 Mar 2021 00:25:10 |
| DataPoint Verified. | (b) (4) (u) (4), (b) (6) | 10 Dec 2020 20:36:10 |
| User entered 'Contact Made (CONTACT MADE)' | Martha Bunnell-Pollak (b) (4) | 02 Nov 2020 16:07:34 |

US3572330

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:21:46

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User signature succeeded. | Milton Haber (b) (4) | 21 Mar 2021 00:25:10 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 10 Dec 2020 20:36:10 |
| User entered empty. | Martha Bunnell-Pollak (b) (4) | 02 Nov 2020 16:07:34 |

US3572330

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:21:46

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User signature succeeded. | Milton Haber (b) (4) | 21 Mar 2021 00:25:10 |
| DataPoint Verified. | (b) (4) (u) (4), (b) (6) | 10 Dec 2020 20:36:15 |
| User entered 'Yes (Y)' | Martha Bunnell-Pollak (b) (4) | 02 Nov 2020 16:07:38 |

US3572330

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:21:46

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User entered 'I' | System | 02 Nov 2020 16:07:38 |

US3572330

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:21:46

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User signature succeeded. | Milton Haber (b) (4) | 21 Mar 2021 00:25:10 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 10 Dec 2020 20:36:27 |
| User entered 'Yes (Y)' | Martha Bunnell-Pollak (b) (4) | 09 Nov 2020 15:39:39 |

US3572330

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:21:46

Date of Contact or Contact Attempt (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User signature succeeded. | Milton Haber (b) (4) | 21 Mar 2021 00:25:10 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 10 Dec 2020 20:36:27 |
| User entered '9 Nov 2020' | Martha Bunnell-Pollak (b) (4) | 09 Nov 2020 15:39:39 |

US3572330

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:21:46

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User signature succeeded. | Milton Haber (b) (4) | 21 Mar 2021 00:25:10 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 10 Dec 2020 20:36:27 |
| User entered 'Contact Made (CONTACT MADE)' | Martha Bunnell-Pollak (b) (4) | 09 Nov 2020 15:39:39 |

US3572330

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:21:46

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User signature succeeded. | Milton Haber (b) (4) | 21 Mar 2021 00:25:10 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 10 Dec 2020 20:36:27 |
| User entered empty. | Martha Bunnell-Pollak (b) (4) | 09 Nov 2020 15:39:39 |

US3572330

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:21:46

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User signature succeeded. | Milton Haber (b) (4) | 21 Mar 2021 00:25:10 |
| DataPoint Verified. | (b) (4) (u) (4), (b) (6) | 10 Dec 2020 20:36:31 |
| User entered 'Yes (Y)' | Martha Bunnell-Pollak (b) (4) | 09 Nov 2020 15:39:45 |

US3572330

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:21:46

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User entered 'l' | System | 09 Nov 2020 15:39:45 |

US3572330

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:21:46

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|--|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User signature succeeded. | Milton Haber (b) (4) | 21 Mar 2021 00:25:10 |
| User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 20Nov2020 is reported under Visit 3 Day 57 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM). | (b) (4) | |
| Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 20Nov2020 is reported under Visit 3 Day 57 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' answered with 'EDC immunogenicity assessment is updated accordingly for Visit 3 Day 57' (Site from DM). | (u) (4), (b) (6) | 11 Feb 2021 18:11:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 02 Feb 2021 17:46:52 |
| User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 20Nov2020 is reported under Visit 3 Day 57 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM). | (b) (4), (b) (6) | 10 Dec 2020 20:36:37 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 03 Dec 2020 14:49:52 |
| | Martha Bunnell-Pollak (b) (4) | 16 Nov 2020 18:31:33 |

US3572330

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:21:46

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

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User signature succeeded. | Milton Haber (b) (4) | 21 Mar 2021 00:25:10 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 10 Dec 2020 20:36:37 |
| User entered '16 Nov 2020' | Martha Bunnell-Pollak (b) (4) | 16 Nov 2020 18:31:33 |

US3572330

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:21:46

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User signature succeeded. | Milton Haber (b) (4) | 21 Mar 2021 00:25:10 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 10 Dec 2020 20:36:37 |
| User entered 'Contact Made (CONTACT MADE)' | Martha Bunnell-Pollak (b) (4) | 16 Nov 2020 18:31:33 |

US3572330

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:21:46

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User signature succeeded. | Milton Haber (b) (4) | 21 Mar 2021 00:25:10 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 10 Dec 2020 20:36:37 |
| User entered empty. | Martha Bunnell-Pollak (b) (4) | 16 Nov 2020 18:31:33 |

US3572330

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:21:46

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User signature succeeded. | Milton Haber (b) (4) | 21 Mar 2021 00:25:10 |
| DataPoint Verified. | (b) (4) (u) (4), (b) (6) | 10 Dec 2020 20:36:41 |
| User entered 'Yes (Y)' | Martha Bunnell-Pollak (b) (4) | 16 Nov 2020 18:31:37 |

US3572330

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:21:46

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User entered 'l' | System | 16 Nov 2020 18:31:37 |

US3572330

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:21:46

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User signature succeeded. | Milton Haber (b) (4) | 21 Mar 2021 00:25:10 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 20:37:28 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 08 Dec 2020 21:09:25 |

US3572330

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:21:46

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User signature succeeded. | Milton Haber (b) (4) | 21 Mar 2021 00:25:10 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 20:37:28 |
| User entered '20 Nov 2020' | (b) (4), (b) (6) | 08 Dec 2020 21:09:25 |

US3572330

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:21:46

[Was visit performed at the participant's home or at the clinic?](#)

| Audit | User | Time (GMT) |
|--------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User signature succeeded. | Milton Haber (b) (4) | 21 Mar 2021 00:25:10 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 20:37:28 |
| User entered 'Clinic (Clinic)' | (b) (4), (b) (6) | 08 Dec 2020 21:09:25 |

US3572330

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:21:46

[Folder OID](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User entered 'VISIT3' | System | 08 Dec 2020 21:09:25 |

US3572330

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:21:46

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User signature succeeded. | Milton Haber (b) (4) | 21 Mar 2021 00:25:10 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 20:37:42 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 08 Dec 2020 21:10:03 |

US3572330

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:21:46

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User signature succeeded. | Milton Haber (b) (4) | 21 Mar 2021 00:25:10 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 20:37:42 |
| User entered '20 Nov 2020' | (b) (4), (b) (6) | 08 Dec 2020 21:10:03 |

US3572330

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:21:46

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User signature succeeded. | Milton Haber (b) (4) | 21 Mar 2021 00:25:10 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 20:37:42 |
| User entered '09:50' | (b) (4), (b) (6) | 08 Dec 2020 21:10:03 |

US3572330

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:21:46

[Vital Signs Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User entered '20 Nov 2020 09:50' | System | 08 Dec 2020 21:10:03 |

US3572330

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:21:46

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User signature succeeded. | Milton Haber (b) (4) | 21 Mar 2021 00:25:10 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 19 Jan 2021 20:37:42 |
| User entered '97.7' F | (b) (4), (b) (6) | 08 Dec 2020 21:10:03 |

US3572330

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:21:46

[Route of measurement](#)

| Audit | User | Time (GMT) |
|------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User signature succeeded. | Milton Haber (b) (4) | 21 Mar 2021 00:25:10 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 20:37:42 |
| User entered 'Other (Other)' | (b) (4), (b) (6) | 08 Dec 2020 21:10:03 |

US3572330

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:21:46

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User signature succeeded. | Milton Haber (b) (4) | 21 Mar 2021 00:25:10 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 20:37:42 |
| User entered 'TEMPORAL' | (b) (4), (b) (6) | 08 Dec 2020 21:10:03 |

US3572330

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:21:46

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User signature succeeded. | Milton Haber (b) (4) | 21 Mar 2021 00:25:10 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 20:37:42 |
| User entered '79' | (b) (4), (b) (6) | 08 Dec 2020 21:10:03 |

US3572330

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:21:46

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User entered 'bpm' | System | 08 Dec 2020 21:10:03 |

US3572330

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:21:46

[Respiratory Rate \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User signature succeeded. | Milton Haber (b) (4) | 21 Mar 2021 00:25:10 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 20:37:42 |
| User entered '20' | (b) (4), (b) (6) | 08 Dec 2020 21:10:03 |

US3572330

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:21:46

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User entered 'breaths/min' | System | 08 Dec 2020 21:10:03 |

US3572330

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:21:46

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User signature succeeded. | Milton Haber (b) (4) | 21 Mar 2021 00:25:10 |
| DataPoint Verified. | (b) (4) (u) (4), (b) (6) | 19 Jan 2021 20:37:42 |
| User entered '139' | (b) (4), (b) (6) | 08 Dec 2020 21:10:03 |

US3572330

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:21:46

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User entered 'mmHg' | System | 08 Dec 2020 21:10:03 |

US3572330

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:21:46

[Diastolic Blood Pressure \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User signature succeeded. | Milton Haber (b) (4) | 21 Mar 2021 00:25:10 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 20:37:42 |
| User entered '85' | (b) (4), (b) (6) | 08 Dec 2020 21:10:03 |

US3572330

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:21:46

[Diastolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User entered 'mmHg' | System | 08 Dec 2020 21:10:03 |

US3572330

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:21:46

[Height \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |

US3572330

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:21:46

Weight (derived)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |

US3572330

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:21:46

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User signature succeeded. | Milton Haber (b) (4) | 21 Mar 2021 00:25:10 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 20:38:07 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 08 Dec 2020 21:10:15 |

US3572330

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:21:46

Date of examination (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User signature succeeded. | Milton Haber (b) (4) | 21 Mar 2021 00:25:10 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 20:38:07 |
| User entered '20 Nov 2020' | (b) (4), (b) (6) | 08 Dec 2020 21:10:15 |

US3572330

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:21:46

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User signature succeeded. | Milton Haber (b) (4) | 21 Mar 2021 00:25:10 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 20:38:11 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 08 Dec 2020 21:10:33 |

US3572330

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:21:46

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User signature succeeded. | Milton Haber (b) (4) | 21 Mar 2021 00:25:10 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 20:38:11 |
| User entered '20 Nov 2020' | (b) (4), (b) (6) | 08 Dec 2020 21:10:33 |

US3572330

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:21:46

Collection time (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User signature succeeded. | Milton Haber (b) (4) | 21 Mar 2021 00:25:10 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 20:38:11 |
| User entered '10:13' | (b) (4), (b) (6) | 08 Dec 2020 21:10:33 |

US3572330

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:21:46

[Collection date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User entered '20 Nov 2020 10:13' | System | 08 Dec 2020 21:10:33 |

US3572330

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:21:46

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User signature succeeded. | Milton Haber (b) (4) | 21 Mar 2021 00:25:10 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 20:38:15 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 08 Dec 2020 21:10:39 |

US3572330

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:21:46

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User entered 'I' | System | 08 Dec 2020 21:10:39 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered 'Day 61' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '18 Nov 2020 00:01' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '22 Nov 2020 23:59' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered 'Day 68' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[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 (58893145452c6200)', Time: '2020-11-25T16:28:03', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: '3aec3208-e1e0-4d34-9bc0-08f2a638db9c' | System | 25 Nov 2020 22:28:28 |
| User entered 'No (N)' | System | 25 Nov 2020 22:28:28 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

Have you been exposed to someone with 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 (58893145452c6200)', Time: '2020-11-25T16:28:17', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: '3aec3208-e1e0-4d34-9bc0-08f2a638db9c' | System | 25 Nov 2020 22:28:28 |
| User entered 'No (N)' | System | 25 Nov 2020 22:28:28 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-11-25T16:28:22', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: '3aec3208-e1e0-4d34-9bc0-08f2a638db9c' User entered '25 Nov 2020 16:28:22' | System | 25 Nov 2020 22:28:28 |
| | System | 25 Nov 2020 22:28:28 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '25 Nov 2020 00:01' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '29 Nov 2020 23:59' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered 'Day 75' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '02 Dec 2020 00:01' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '06 Dec 2020 23:59' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered 'Day 82' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '09 Dec 2020 00:01' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '13 Dec 2020 23:59' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered 'Day 89' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[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 (58893145452c6200)', Time: '2020-12-19T20:15:55', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: 'e793aeca-8b8a-492e-803d-e009b07f0107' | System | 20 Dec 2020 02:16:18 |
| User entered 'No (N)' | System | 20 Dec 2020 02:16:18 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

Have you been exposed to someone with 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 (58893145452c6200)', Time: '2020-12-19T20:16:09', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: 'e793aeca-8b8a-492e-803d-e009b07f0107' | System | 20 Dec 2020 02:16:18 |
| User entered 'No (N)' | System | 20 Dec 2020 02:16:18 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2020-12-19T20:16:13', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: 'e793aeca-8b8a-492e-803d-e009b07f0107' | System | 20 Dec 2020 02:16:18 |
| User entered '19 Dec 2020 20:16:13' | System | 20 Dec 2020 02:16:18 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '16 Dec 2020 00:01' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '20 Dec 2020 23:59' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered 'Day 96' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '23 Dec 2020 00:01' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '27 Dec 2020 23:59' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered 'Day 103' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '30 Dec 2020 00:01' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '03 Jan 2021 23:59' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered 'Day 110' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[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 (58893145452c6200)', Time: '2021-01-07T11:43:04', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: '4570d203-fd89-4f04-94ed-3b242af5692b' | System | 07 Jan 2021 17:43:28 |
| User entered 'No (N)' | System | 07 Jan 2021 17:43:28 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

Have you been exposed to someone with 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 (58893145452c6200)', Time: '2021-01-07T11:43:17', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: '4570d203-fd89-4f04-94ed-3b242af5692b' | System | 07 Jan 2021 17:43:28 |
| User entered 'No (N)' | System | 07 Jan 2021 17:43:28 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2021-01-07T11:43:21', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: '4570d203-fd89-4f04-94ed-3b242af5692b' User entered '07 Jan 2021 11:43:21' | System | 07 Jan 2021 17:43:28 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '06 Jan 2021 00:01' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '10 Jan 2021 23:59' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered 'Day 117' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '13 Jan 2021 00:01' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '17 Jan 2021 23:59' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered 'Day 124' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '20 Jan 2021 00:01' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '24 Jan 2021 23:59' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered 'Day 131' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '27 Jan 2021 00:01' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '31 Jan 2021 23:59' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered 'Day 138' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '03 Feb 2021 00:01' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '07 Feb 2021 23:59' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered 'Day 145' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[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 (58893145452c6200)', Time: '2021-02-10T00:06:46', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: '44a5df29-8a4e-426f-a63b-fca7070b949c' | System | 10 Feb 2021 06:06:58 |
| User entered 'No (N)' | System | 10 Feb 2021 06:06:58 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

Have you been exposed to someone with 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 (58893145452c6200)', Time: '2021-02-10T00:06:52', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: '44a5df29-8a4e-426f-a63b-fea7070b949c' | System | 10 Feb 2021 06:06:58 |
| User entered 'No (N)' | System | 10 Feb 2021 06:06:58 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2021-02-10T00:06:55', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: '44a5df29-8a4e-426f-a63b-fea7070b949c' | System | 10 Feb 2021 06:06:58 |
| User entered '10 Feb 2021 00:06:55' | System | 10 Feb 2021 06:06:58 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '10 Feb 2021 00:01' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '14 Feb 2021 23:59' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered 'Day 152' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[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 (58893145452c6200)', Time: '2021-02-21T19:51:28', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: '49e10aac-a59d-48f0-a23f-5c058aab6cd7' | System | 22 Feb 2021 01:51:39 |
| User entered 'No (N)' | System | 22 Feb 2021 01:51:39 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

Have you been exposed to someone with 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 (58893145452c6200)', Time: '2021-02-21T19:51:33', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: '49e10aac-a59d-48f0-a23f-5c058aab6cd7' | System | 22 Feb 2021 01:51:39 |
| User entered 'No (N)' | System | 22 Feb 2021 01:51:39 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2021-02-21T19:51:36', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: '49e10aac-a59d-48f0-a23f-5c058aab6cd7' | System | 22 Feb 2021 01:51:39 |
| User entered '21 Feb 2021 19:51:36' | System | 22 Feb 2021 01:51:39 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '17 Feb 2021 00:01' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '21 Feb 2021 23:59' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered 'Day 159' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[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 (58893145452c6200)', Time: '2021-02-27T19:46:12-06:00', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: 'f2ce3b4d-2a9c-4f68-90f9-8c4e5a73ddd9' User entered 'No (N)' | System | 28 Feb 2021 01:46:23 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

Have you been exposed to someone with 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 (58893145452c6200)', Time: '2021-02-27T19:46:16-06:00', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: 'f2ce3b4d-2a9c-4f68-90f9-8c4e5a73ddd9' | System | 28 Feb 2021 01:46:23 |
| User entered 'No (N)' | System | 28 Feb 2021 01:46:23 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2021-02-27T19:46:19-06:00', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: 'f2ce3b4d-2a9c-4f68-90f9-8c4e5a73ddd9' | System | 28 Feb 2021 01:46:23 |
| User entered '27 Feb 2021 19:46:19' | System | 28 Feb 2021 01:46:23 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '24 Feb 2021 00:01' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '28 Feb 2021 23:59' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered 'Day 166' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '03 Mar 2021 00:01' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '07 Mar 2021 23:59' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered 'Day 173' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '10 Mar 2021 00:01' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '14 Mar 2021 23:59' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered 'Day 180' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '17 Mar 2021 00:01' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '21 Mar 2021 23:59' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered 'Day 187' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[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 (e4d793f350f898b6)', Time: '2021-03-24T01:50:59-05:00', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: 'c76da12f-f153-4a09-a8aa-784ffe6d965c' | System | 24 Mar 2021 06:51:19 |
| User entered 'No (N)' | System | 24 Mar 2021 06:51:19 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Have you been exposed to someone with 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 (e4d793f350f898b6)', Time: '2021-03-24T01:51:07-05:00', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: 'c76da12f-f153-4a09-a8aa-784ffe6d965c' | System | 24 Mar 2021 06:51:19 |
| User entered 'No (N)' | System | 24 Mar 2021 06:51:19 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4d793f350f898b6)', Time: '2021-03-24T01:51:11-05:00', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: 'c76da12f-f153-4a09-a8aa-784ffe6d965c' User entered '24 Mar 2021 01:51:11' | System | 24 Mar 2021 06:51:19 |
| | System | 24 Mar 2021 06:51:19 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '24 Mar 2021 00:01' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '28 Mar 2021 23:59' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered 'Day 194' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[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 (e4d793f350f898b6)', Time: '2021-03-31T00:01:34-05:00', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: 'f4772002-c478-465a-973a-86dfba19e269' | System | 31 Mar 2021 05:01:46 |
| User entered 'No (N)' | System | 31 Mar 2021 05:01:46 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Have you been exposed to someone with 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 (e4d793f350f898b6)', Time: '2021-03-31T00:01:38-05:00', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: 'f4772002-c478-465a-973a-86dfba19e269' | System | 31 Mar 2021 05:01:46 |
| User entered 'No (N)' | System | 31 Mar 2021 05:01:46 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4d793f350f898b6)', Time: '2021-03-31T00:01:42-05:00', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: 'f4772002-c478-465a-973a-86dfba19e269' User entered '31 Mar 2021 00:01:42' | System | 31 Mar 2021 05:01:46 |
| | System | 31 Mar 2021 05:01:46 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '31 Mar 2021 00:01' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '04 Apr 2021 23:59' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered 'Day 201' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[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 (e4d793f350f898b6)', Time: '2021-04-07T00:01:28-05:00', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: '77d705f4-28b5-4c48-ba88-ccf8d3a71eee' User entered 'No (N)' | System | 07 Apr 2021 05:01:46 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

Have you been exposed to someone with 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 (e4d793f350f898b6)', Time: '2021-04-07T00:01:38-05:00', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: '77d705f4-28b5-4c48-ba88-ccf8d3a71eee' | System | 07 Apr 2021 05:01:46 |
| User entered 'No (N)' | System | 07 Apr 2021 05:01:46 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4d793f350f898b6)', Time: '2021-04-07T00:01:42-05:00', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: '77d705f4-28b5-4c48-ba88-ccf8d3a71eee' User entered '07 Apr 2021 00:01:42' | System | 07 Apr 2021 05:01:46 |
| | System | 07 Apr 2021 05:01:46 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '07 Apr 2021 00:01' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '11 Apr 2021 23:59' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered 'Day 208' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[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 (e4d793f350f898b6)', Time: '2021-04-15T22:14:16-05:00', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: '06b427fa-8d50-40cc-a6d7-d3563d9b6ca6' | System | 16 Apr 2021 03:14:28 |
| User entered 'No (N)' | System | 16 Apr 2021 03:14:28 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Have you been exposed to someone with 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 (e4d793f350f898b6)', Time: '2021-04-15T22:14:20-05:00', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: '06b427fa-8d50-40cc-a6d7-d3563d9b6ca6' | System | 16 Apr 2021 03:14:28 |
| User entered 'No (N)' | System | 16 Apr 2021 03:14:28 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4d793f350f898b6)', Time: '2021-04-15T22:14:24-05:00', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: '06b427fa-8d50-40cc-a6d7-d3563d9b6ca6' | System | 16 Apr 2021 03:14:28 |
| User entered '15 Apr 2021 22:14:24' | System | 16 Apr 2021 03:14:28 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '14 Apr 2021 00:01' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '18 Apr 2021 23:59' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered 'Day 215' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[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 (e4d793f350f898b6)', Time: '2021-04-21T09:17:56-05:00', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: 'e27af70a-a5ee-419e-bb51-63bb29e070d1' | System | 21 Apr 2021 14:18:07 |
| User entered 'No (N)' | System | 21 Apr 2021 14:18:07 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Have you been exposed to someone with 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 (e4d793f350f898b6)', Time: '2021-04-21T09:17:59-05:00', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: 'e27af70a-a5ee-419e-bb51-63bb29e070d1' | System | 21 Apr 2021 14:18:07 |
| User entered 'No (N)' | System | 21 Apr 2021 14:18:07 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4d793f350f898b6)', Time: '2021-04-21T09:18:01-05:00', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: 'e27af70a-a5ee-419e-bb51-63bb29e070d1' | System | 21 Apr 2021 14:18:07 |
| User entered '21 Apr 2021 09:18:01' | System | 21 Apr 2021 14:18:07 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '21 Apr 2021 00:01' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '25 Apr 2021 23:59' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered 'Day 222' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[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 (e4d793f350f898b6)', Time: '2021-05-02T10:43:40-05:00', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: '1f1982de-bd08-4b59-9378-369aeb75a76e' | System | 02 May 2021 15:43:53 |
| User entered 'No (N)' | System | 02 May 2021 15:43:53 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Have you been exposed to someone with 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 (e4d793f350f898b6)', Time: '2021-05-02T10:43:43-05:00', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: '1f1982de-bd08-4b59-9378-369aeb75a76e' | System | 02 May 2021 15:43:53 |
| User entered 'No (N)' | System | 02 May 2021 15:43:53 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e4d793f350f898b6)', Time: '2021-05-02T10:43:45-05:00', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: '1f1982de-bd08-4b59-9378-369aeb75a76e' | System | 02 May 2021 15:43:53 |
| User entered '02 May 2021 10:43:45' | System | 02 May 2021 15:43:53 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '28 Apr 2021 00:01' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '02 May 2021 23:59' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered 'Day 229' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '05 May 2021 00:01' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '09 May 2021 23:59' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered 'Day 236' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '12 May 2021 00:01' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '16 May 2021 23:59' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered 'Day 243' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '19 May 2021 00:01' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '23 May 2021 23:59' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered 'Day 250' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '26 May 2021 00:01' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '30 May 2021 23:59' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered 'Day 257' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '02 Jun 2021 00:01' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '06 Jun 2021 23:59' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered 'Day 264' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '09 Jun 2021 00:01' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '13 Jun 2021 23:59' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered 'Day 271' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '16 Jun 2021 00:01' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '20 Jun 2021 23:59' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered 'Day 278' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '23 Jun 2021 00:01' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '27 Jun 2021 23:59' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered 'Day 285' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '30 Jun 2021 00:01' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '04 Jul 2021 23:59' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered 'Day 292' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '07 Jul 2021 00:01' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '11 Jul 2021 23:59' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered 'Day 299' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '14 Jul 2021 00:01' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '18 Jul 2021 23:59' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered 'Day 306' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '21 Jul 2021 00:01' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '25 Jul 2021 23:59' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered 'Day 313' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '28 Jul 2021 00:01' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '01 Aug 2021 23:59' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered 'Day 320' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '04 Aug 2021 00:01' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '08 Aug 2021 23:59' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered 'Day 327' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '11 Aug 2021 00:01' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '15 Aug 2021 23:59' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered 'Day 334' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '18 Aug 2021 00:01' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '22 Aug 2021 23:59' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered 'Day 341' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '25 Aug 2021 00:01' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '29 Aug 2021 23:59' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered 'Day 348' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '01 Sep 2021 00:01' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '05 Sep 2021 23:59' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered 'Day 355' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '08 Sep 2021 00:01' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '12 Sep 2021 23:59' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered 'Day 362' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '15 Sep 2021 00:01' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '19 Sep 2021 23:59' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered 'Day 369' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '22 Sep 2021 00:01' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '26 Sep 2021 23:59' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered 'Day 376' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '29 Sep 2021 00:01' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '03 Oct 2021 23:59' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered 'Day 383' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '06 Oct 2021 00:01' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '10 Oct 2021 23:59' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered 'Day 390' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '13 Oct 2021 00:01' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '17 Oct 2021 23:59' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered 'Day 397' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '20 Oct 2021 00:01' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '24 Oct 2021 23:59' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered 'Day 404' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '27 Oct 2021 00:01' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '31 Oct 2021 23:59' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered 'Day 411' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '03 Nov 2021 00:01' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '07 Nov 2021 23:59' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered 'Day 418' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '10 Nov 2021 00:01' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '14 Nov 2021 23:59' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered 'Day 425' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '17 Nov 2021 00:01' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '21 Nov 2021 23:59' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered 'Day 432' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '24 Nov 2021 00:01' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '28 Nov 2021 23:59' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered 'Day 439' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '01 Dec 2021 00:01' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '05 Dec 2021 23:59' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered 'Day 446' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '08 Dec 2021 00:01' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '12 Dec 2021 23:59' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered 'Day 453' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '15 Dec 2021 00:01' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '19 Dec 2021 23:59' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered 'Day 460' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '22 Dec 2021 00:01' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '26 Dec 2021 23:59' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered 'Day 467' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '29 Dec 2021 00:01' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '02 Jan 2022 23:59' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered 'Day 474' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '05 Jan 2022 00:01' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '09 Jan 2022 23:59' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered 'Day 481' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '12 Jan 2022 00:01' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '16 Jan 2022 23:59' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered 'Day 488' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '19 Jan 2022 00:01' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '23 Jan 2022 23:59' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered 'Day 495' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '26 Jan 2022 00:01' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '30 Jan 2022 23:59' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered 'Day 502' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '02 Feb 2022 00:01' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '06 Feb 2022 23:59' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered 'Day 509' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '09 Feb 2022 00:01' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '13 Feb 2022 23:59' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered 'Day 516' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '16 Feb 2022 00:01' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '20 Feb 2022 23:59' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered 'Day 523' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '23 Feb 2022 00:01' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '27 Feb 2022 23:59' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered 'Day 530' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '02 Mar 2022 00:01' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '06 Mar 2022 23:59' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered 'Day 537' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '09 Mar 2022 00:01' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '13 Mar 2022 23:59' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered 'Day 544' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '16 Mar 2022 00:01' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '20 Mar 2022 23:59' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered 'Day 551' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '23 Mar 2022 00:01' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '27 Mar 2022 23:59' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered 'Day 558' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '30 Mar 2022 00:01' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '03 Apr 2022 23:59' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered 'Day 565' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '06 Apr 2022 00:01' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '10 Apr 2022 23:59' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered 'Day 572' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '13 Apr 2022 00:01' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '17 Apr 2022 23:59' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered 'Day 579' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '20 Apr 2022 00:01' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '24 Apr 2022 23:59' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered 'Day 586' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '27 Apr 2022 00:01' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '01 May 2022 23:59' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered 'Day 593' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '04 May 2022 00:01' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '08 May 2022 23:59' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered 'Day 600' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '11 May 2022 00:01' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '15 May 2022 23:59' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered 'Day 607' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '18 May 2022 00:01' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '22 May 2022 23:59' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered 'Day 614' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '25 May 2022 00:01' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '29 May 2022 23:59' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered 'Day 621' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '01 Jun 2022 00:01' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '05 Jun 2022 23:59' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered 'Day 628' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '08 Jun 2022 00:01' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '12 Jun 2022 23:59' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered 'Day 635' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '15 Jun 2022 00:01' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '19 Jun 2022 23:59' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered 'Day 642' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '22 Jun 2022 00:01' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '26 Jun 2022 23:59' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered 'Day 649' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '29 Jun 2022 00:01' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '03 Jul 2022 23:59' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered 'Day 656' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '06 Jul 2022 00:01' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '10 Jul 2022 23:59' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered 'Day 663' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '13 Jul 2022 00:01' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '17 Jul 2022 23:59' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered 'Day 670' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '20 Jul 2022 00:01' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '24 Jul 2022 23:59' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered 'Day 677' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '27 Jul 2022 00:01' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '31 Jul 2022 23:59' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered 'Day 684' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '03 Aug 2022 00:01' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '07 Aug 2022 23:59' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered 'Day 691' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '10 Aug 2022 00:01' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '14 Aug 2022 23:59' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered 'Day 698' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '17 Aug 2022 00:01' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '21 Aug 2022 23:59' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered 'Day 705' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '24 Aug 2022 00:01' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '28 Aug 2022 23:59' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered 'Day 712' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '31 Aug 2022 00:01' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '04 Sep 2022 23:59' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered 'Day 719' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '07 Sep 2022 00:01' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '11 Sep 2022 23:59' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered 'Day 726' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '14 Sep 2022 00:01' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '18 Sep 2022 23:59' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered 'Day 733' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '21 Sep 2022 00:01' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '25 Sep 2022 23:59' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered 'Day 740' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '28 Sep 2022 00:01' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '02 Oct 2022 23:59' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered 'Day 747' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '05 Oct 2022 00:01' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '09 Oct 2022 23:59' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered 'Day 754' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '12 Oct 2022 00:01' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '16 Oct 2022 23:59' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered 'Day 761' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '19 Oct 2022 00:01' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '23 Oct 2022 23:59' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered 'Day 768' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '26 Oct 2022 00:01' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '30 Oct 2022 23:59' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered 'Day 775' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '02 Nov 2022 00:01' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '06 Nov 2022 23:59' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered 'Day 782' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '09 Nov 2022 00:01' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '13 Nov 2022 23:59' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered 'Day 789' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '16 Nov 2022 00:01' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '20 Nov 2022 23:59' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered 'Day 796' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '23 Nov 2022 00:01' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:46

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 20 Nov 2020 09:54:40 |
| Amendment Manager: User entered '27 Nov 2022 23:59' | System | 20 Nov 2020 09:54:40 |

US3572330

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 08:21:46

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 18:27:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2021-02-27T19:46:04-06:00', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: 'ff02fdbe-caae-4ff4-b88a-b145d6b92c1e' | System | 28 Feb 2021 01:46:11 |
| User entered 'No (N)' | System | 28 Feb 2021 01:46:11 |

US3572330

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 08:21:46

[Date & Time of Submission](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 18:27:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (58893145452c6200)', Time: '2021-02-27T19:46:07-06:00', User OID: 'PatientReportedOutcome (US3572330)', ODM File OID: 'ff02fdbe-caae-4ff4-b88a-b145d6b92c1e' | System | 28 Feb 2021 01:46:11 |
| User entered '27 Feb 2021 19:46:07' | System | 28 Feb 2021 01:46:11 |

US3572330

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:21:46

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User signature succeeded. | Milton Haber (b) (4) | 21 Mar 2021 04:25:17 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 20:38:38 |
| User entered 'Yes (Y)' | Martha Bunnell-Pollak (b) (4) | 18 Dec 2020 16:54:06 |

US3572330

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:21:46

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

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User signature succeeded. | Milton Haber (b) (4) | 21 Mar 2021 04:25:17 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 20:38:38 |
| User entered '18 Dec 2020' | Martha Bunnell-Pollak (b) (4) | 18 Dec 2020 16:54:06 |

US3572330

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:21:46

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User signature succeeded. | Milton Haber (b) (4) | 21 Mar 2021 04:25:17 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 20:38:38 |
| User entered 'Contact Made (CONTACT MADE)' | Martha Bunnell-Pollak (b) (4) | 18 Dec 2020 16:54:06 |

US3572330

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:21:46

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User signature succeeded. | Milton Haber (b) (4) | 21 Mar 2021 04:25:17 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Jan 2021 20:38:38 |
| User entered empty. | Martha Bunnell-Pollak (b) (4) | 18 Dec 2020 16:54:06 |

US3572330

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:21:46

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User signature succeeded. | Milton Haber (b) (4) | 21 Mar 2021 04:25:17 |
| DataPoint Verified. | (b) (4) (u) (4), (b) (6) | 19 Jan 2021 20:38:41 |
| User entered 'Yes (Y)' | Martha Bunnell-Pollak (b) (4) | 18 Dec 2020 16:54:12 |

US3572330

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:21:46

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 14:40:44 |
| User entered 'I' | System | 18 Dec 2020 16:54:12 |

US3572330

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:21:46

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 11:27:26 |
| DataPoint Verified. | (b) (4), (b) (6) | 11 Apr 2021 22:21:43 |
| User signature succeeded. | Milton Haber (b) (4) | 03 Apr 2021 05:07:34 |
| User entered 'Yes (Y)' | (b) (4) Martha Bunnell-Pollak (b) (4) | 26 Jan 2021 18:49:12 |

US3572330

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:21:46

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

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 11:27:26 |
| DataPoint Verified. | (b) (4), (b) (6) | 11 Apr 2021 22:21:43 |
| User signature succeeded. | Milton Haber (b) (4) | 03 Apr 2021 05:07:34 |
| User entered '26 Jan 2021' | (b) (4) Martha Bunnell-Pollak (b) (4) | 26 Jan 2021 18:49:12 |

US3572330

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:21:46

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 11:27:26 |
| DataPoint Verified. | (b) (4), (b) (6) | 11 Apr 2021 22:21:43 |
| User signature succeeded. | Milton Haber (b) (4) | 03 Apr 2021 05:07:34 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4) Martha Bunnell-Pollak (b) (4) | 26 Jan 2021 18:49:12 |

US3572330

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:21:46

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 11:27:26 |
| DataPoint Verified. | (b) (4), (b) (6) | 11 Apr 2021 22:21:43 |
| User signature succeeded. | Milton Haber (b) (4) | 03 Apr 2021 05:07:34 |
| User entered empty. | (b) (4) Martha Bunnell-Pollak (b) (4) | 26 Jan 2021 18:49:12 |

US3572330

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:21:46

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 11:27:26 |
| DataPoint Verified. | (b) (4), (b) (6) | 11 Apr 2021 22:21:52 |
| User signature succeeded. | Milton Haber (b) (4) | 03 Apr 2021 05:07:34 |
| User entered 'Yes (Y)' | (b) (4) Martha Bunnell-Pollak (b) (4) | 26 Jan 2021 18:49:16 |

US3572330

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:21:46

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 11:27:26 |
| User entered 'l' | System | 26 Jan 2021 18:49:16 |

US3572330

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:21:46

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 11:27:26 |
| DataPoint Verified. | (b) (4), (b) (6) | 11 Apr 2021 22:22:05 |
| User signature succeeded. | Milton Haber (b) (4) | 03 Apr 2021 05:07:34 |
| User entered 'Yes (Y)' | (b) (4) Martha Bunnell-Pollak (b) (4) | 22 Feb 2021 21:04:07 |

US3572330

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:21:46

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

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 11:27:26 |
| DataPoint Verified. | (b) (4), (b) (6) | 11 Apr 2021 22:22:05 |
| User signature succeeded. | Milton Haber (b) (4) | 03 Apr 2021 05:07:34 |
| User entered '22 Feb 2021' | (b) (4) Martha Bunnell-Pollak (b) (4) | 22 Feb 2021 21:04:07 |

US3572330

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:21:46

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 11:27:26 |
| DataPoint Verified. | (b) (4), (b) (6) | 11 Apr 2021 22:22:05 |
| User signature succeeded. | Milton Haber (b) (4) | 03 Apr 2021 05:07:34 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4) Martha Bunnell-Pollak (b) (4) | 22 Feb 2021 21:04:07 |

US3572330

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:21:46

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 11:27:26 |
| DataPoint Verified. | (b) (4), (b) (6) | 11 Apr 2021 22:22:05 |
| User signature succeeded. | Milton Haber (b) (4) | 03 Apr 2021 05:07:34 |
| User entered empty. | (b) (4) Martha Bunnell-Pollak (b) (4) | 22 Feb 2021 21:04:07 |

US3572330

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:21:46

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 11:27:26 |
| DataPoint Verified. | (b) (4), (b) (6) | 11 Apr 2021 22:21:59 |
| User signature succeeded. | Milton Haber (b) (4) | 03 Apr 2021 05:07:34 |
| User entered 'Yes (Y)' | (b) (4) Martha Bunnell-Pollak (b) (4) | 22 Feb 2021 21:04:10 |

US3572330

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:21:46

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 11:27:26 |
| User entered 'l' | System | 22 Feb 2021 21:04:10 |

US3572330

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:21:46

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 11:27:26 |
| DataPoint Verified. | (b) (4), (b) (6) | 11 Apr 2021 22:22:13 |
| User signature succeeded. | Milton Haber (b) (4) | 03 Apr 2021 05:07:34 |
| User entered 'Yes (Y)' | (b) (4) Martha Bunnell-Pollak (b) (4) | 22 Mar 2021 13:54:10 |

US3572330

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:21:46

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

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 11:27:26 |
| DataPoint Verified. | (b) (4), (b) (6) | 11 Apr 2021 22:22:13 |
| User signature succeeded. | Milton Haber (b) (4) | 03 Apr 2021 05:07:34 |
| User entered '22 Mar 2021' | (b) (4) Martha Bunnell-Pollak (b) (4) | 22 Mar 2021 13:54:10 |

US3572330

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:21:46

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 11:27:26 |
| DataPoint Verified. | (b) (4), (b) (6) | 11 Apr 2021 22:22:13 |
| User signature succeeded. | Milton Haber (b) (4) | 03 Apr 2021 05:07:34 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4) Martha Bunnell-Pollak (b) (4) | 22 Mar 2021 13:54:10 |

US3572330

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:21:46

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 11:27:26 |
| DataPoint Verified. | (b) (4), (b) (6) | 11 Apr 2021 22:22:13 |
| User signature succeeded. | Milton Haber (b) (4) | 03 Apr 2021 05:07:34 |
| User entered empty. | (b) (4) Martha Bunnell-Pollak (b) (4) | 22 Mar 2021 13:54:10 |

US3572330

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:21:46

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 11:27:26 |
| DataPoint Verified. | (b) (4), (b) (6) | 11 Apr 2021 22:23:56 |
| User signature succeeded. | Milton Haber (b) (4) | 03 Apr 2021 05:07:34 |
| User entered 'Yes (Y)' | (b) (4) Martha Bunnell-Pollak (b) (4) | 22 Mar 2021 13:54:16 |

US3572330

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:21:46

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 11:27:26 |
| User entered 'l' | System | 22 Mar 2021 13:54:16 |

US3572330

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:21:46

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4) | 03 May 2021 15:01:42 |
| User entered 'Yes (Y)' | (b) (4) (u) (4), (b) (6) | 30 Apr 2021 20:02:36 |

US3572330

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:21:46

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4) | 03 May 2021 15:01:42 |
| User entered '27 Apr 2021' | (b) (4) (u) (4), (b) (6) | 30 Apr 2021 20:02:36 |

US3572330

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:21:46

Was visit performed at the participant's home or at the clinic?

| Audit | User | Time (GMT) |
|--------------------------------|-----------------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4) | 03 May 2021 15:01:42 |
| User entered 'Clinic (Clinic)' | (b) (4) (u) (4), (b) (6) | 30 Apr 2021 20:02:36 |

US3572330

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:21:46

[Folder OID](#)

| Audit | User | Time (GMT) |
|-----------------------|--------|----------------------|
| User entered 'VISIT4' | System | 30 Apr 2021 20:02:36 |

US3572330

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:21:46

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4) | 03 May 2021 15:01:42 |
| User entered 'No (N)' | (b) (4) (u) (4), (b) (6) | 30 Apr 2021 20:02:54 |

US3572330

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:21:46

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4) | 03 May 2021 15:01:42 |
| User entered empty. | (b) (4) (u) (4), (b) (6) | 30 Apr 2021 20:02:54 |

US3572330

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:21:46

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4) | 03 May 2021 15:01:42 |
| User entered empty. | (b) (4) (u) (4), (b) (6) | 30 Apr 2021 20:02:54 |

US3572330

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:21:46

[Vital Signs Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 30 Apr 2021 20:02:54 |

US3572330

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:21:46

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4) | 03 May 2021 15:01:42 |
| User entered empty. | (b) (4) (u) (4), (b) (6) | 30 Apr 2021 20:02:54 |

US3572330

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:21:46

[Route of measurement](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4) | 03 May 2021 15:01:42 |
| User entered empty. | (b) (4) (u) (4), (b) (6) | 30 Apr 2021 20:02:54 |

US3572330

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:21:46

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4) | 03 May 2021 15:01:42 |
| User entered empty. | (b) (4) (u) (4), (b) (6) | 30 Apr 2021 20:02:54 |

US3572330

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:21:46

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4) | 03 May 2021 15:01:42 |
| User entered empty. | (b) (4) (u) (4), (b) (6) | 30 Apr 2021 20:02:54 |

US3572330

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:21:46

[Pulse units](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 30 Apr 2021 20:02:54 |

US3572330

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:21:46

[Respiratory Rate \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4) | 03 May 2021 15:01:42 |
| User entered empty. | (b) (4) (u) (4), (b) (6) | 30 Apr 2021 20:02:54 |

US3572330

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:21:46

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 30 Apr 2021 20:02:54 |

US3572330

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:21:46

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4) | 03 May 2021 15:01:42 |
| User entered empty. | (b) (4) (u) (4), (b) (6) | 30 Apr 2021 20:02:54 |

US3572330

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:21:46

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 30 Apr 2021 20:02:54 |

US3572330

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:21:46

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4) | 03 May 2021 15:01:42 |
| User entered empty. | (b) (4) (u) (4), (b) (6) | 30 Apr 2021 20:02:54 |

US3572330

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:21:46

[Diastolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 30 Apr 2021 20:02:54 |

US3572330

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:21:46

Was the physical examination performed?

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4) | 03 May 2021 15:01:42 |
| User entered 'No (N)' | (b) (4) (u) (4), (b) (6) | 30 Apr 2021 20:03:25 |

US3572330

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:21:46

Date of examination (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4) | 03 May 2021 15:01:42 |
| User entered empty. | (b) (4) (u) (4), (b) (6) | 30 Apr 2021 20:03:25 |

US3572330

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:21:46

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4) | 03 May 2021 15:01:42 |
| | (b) (4) | |
| User closed query 'Data is required. Please complete.' (Site from System). | System | 30 Apr 2021 20:05:26 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 30 Apr 2021 20:05:26 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | (b) (4), (b) (6) | 30 Apr 2021 20:05:26 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 30 Apr 2021 20:03:43 |
| User entered empty. | (b) (4), (b) (6) | 30 Apr 2021 20:03:43 |

US3572330

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:21:46

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4) | 03 May 2021 15:01:42 |
| User entered '27 Apr 2021' reason for change: Data Entry Error | (b) (4) | |
| | (b) (4), (b) (6) | 30 Apr 2021 20:05:26 |
| User entered empty. | (b) (4), (b) (6) | 30 Apr 2021 20:03:43 |

US3572330

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:21:46

[Collection time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4) | 03 May 2021 15:01:42 |
| User entered '10:14' reason for change: Data Entry Error | (b) (4) (u) (4), (b) (6) | 30 Apr 2021 20:05:26 |
| User entered empty. | (b) (4), (b) (6) | 30 Apr 2021 20:03:43 |

US3572330

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:21:46

[Collection date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered '27 Apr 2021 10:14' | System | 30 Apr 2021 20:05:26 |
| User entered empty. | System | 30 Apr 2021 20:03:43 |

US3572330

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:21:46

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Milton Haber (b) (4) | 03 May 2021 15:01:42 |
| User entered 'Yes (Y)' | (b) (4) (u) (4), (b) (6) | 30 Apr 2021 20:05:30 |

US3572330

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:21:46

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 30 Apr 2021 20:05:30 |

US3572330

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

Form: Visit Date

Generated On: 10 Jun 2021 08:21:46

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 04:02:55 |
| User signature succeeded. | Milton Haber (b) (4) | 03 Apr 2021 05:07:34 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 01 Apr 2021 15:20:09 |

US3572330

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

Form: Visit Date

Generated On: 10 Jun 2021 08:21:46

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 04:02:55 |
| User signature succeeded. | Milton Haber (b) (4) | 03 Apr 2021 05:07:34 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 01 Apr 2021 15:20:09 |

US3572330

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

Form: Visit Date

Generated On: 10 Jun 2021 08:21:46

[Was visit performed at the participant's home or at the clinic?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 04:02:55 |
| User signature succeeded. | Milton Haber (b) (4) | 03 Apr 2021 05:07:34 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 01 Apr 2021 15:20:09 |

US3572330

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

Form: Visit Date

Generated On: 10 Jun 2021 08:21:46

[Folder OID](#)

| Audit | User | Time (GMT) |
|------------------------------|--------|----------------------|
| User entered 'UNBLND_DECIDE' | System | 01 Apr 2021 15:20:09 |

US3572330

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

Form: Unblinding

Generated On: 10 Jun 2021 08:21:46

Date of updated informed consent (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| User closed query 'Per CDM:Per sponsor review, the date of updated informed consent' and 'N/A - Subject Unblinded under Amendment 5 and Discontinued from Study' cannot both be blank. Please either update date subject signed updated informed consent or if Subject discontinued from the study under Amendment 5, tick the box.' (Site from DM). | (b) (4), (b) (6) | 23 Apr 2021 10:09:17 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 04:02:50 |
| Query 'Per CDM:Per sponsor review, the date of updated informed consent' and 'N/A - Subject Unblinded under Amendment 5 and Discontinued from Study' cannot both be blank. Please either update date subject signed updated informed consent or if Subject discontinued from the study under Amendment 5, tick the box.' answered with 'Last Visit was performed on 20NOV2020' (Site from DM). | (b) (4), (b) (6) | 09 Apr 2021 16:57:01 |
| User opened query 'Per CDM:Per sponsor review, the date of updated informed consent' and 'N/A - Subject Unblinded under Amendment 5 and Discontinued from Study' cannot both be blank. Please either update date subject signed updated informed consent or if Subject discontinued from the study under Amendment 5, tick the box.' (Site from DM). | (b) (4), (b) (6) | 08 Apr 2021 04:47:05 |
| User signature succeeded. | Milton Haber (b) (4) | 03 Apr 2021 05:07:34 |
| User entered empty. | (b) (4) (u) (4), (b) (6) | 01 Apr 2021 15:20:25 |

US3572330

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

Form: Unblinding

Generated On: 10 Jun 2021 08:21:46

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

| Audit | User | Time (GMT) |
|---|----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 04:02:50 |
| User signature succeeded. | Milton Haber (b) (4) | 15 Apr 2021 19:17:24 |
| User closed query 'Per CDM: 'NA unblinded under A5 and study discontinued' is not ticked and consent date is blank. Please review as one of these fields should be completed. ' (Site from DM). | (b) (4) | 15 Apr 2021 15:05:45 |
| Query 'Per CDM: 'NA unblinded under A5 and study discontinued' is not ticked and consent date is blank. Please review as one of these fields should be completed. ' answered with 'Updated' (Site from DM). | (b) (4), (b) (6) | 14 Apr 2021 16:51:31 |
| Signature has been broken. | (b) (4), (b) (6) | 14 Apr 2021 16:51:23 |
| User entered '1' reason for change: Data Entry Error | (b) (4), (b) (6) | 14 Apr 2021 16:51:23 |
| User opened query 'Per CDM: 'NA unblinded under A5 and study discontinued' is not ticked and consent date is blank. Please review as one of these fields should be completed. ' (Site from DM). | (b) (4), (b) (6) | 13 Apr 2021 07:26:08 |
| User signature succeeded. | Milton Haber (b) (4) | 03 Apr 2021 05:07:34 |
| User entered '0' | (b) (4) | 01 Apr 2021 15:20:25 |

US3572330

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

Form: Unblinding

Generated On: 10 Jun 2021 08:21:46

[Was the participant unblinded?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 04:02:50 |
| User signature succeeded. | Milton Haber (b) (4) | 03 Apr 2021 05:07:34 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 01 Apr 2021 15:20:25 |

US3572330

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

Form: Unblinding

Generated On: 10 Jun 2021 08:21:46

[Under what version of the Protocol was the Participant unblinded?](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 04:02:50 |
| User signature succeeded. | Milton Haber (b) (4) | 03 Apr 2021 05:07:34 |
| User entered 'Amendment 5 (Amendment 5)' | (b) (4) (b) (4), (b) (6) | 01 Apr 2021 15:20:25 |

US3572330

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

Form: Unblinding

Generated On: 10 Jun 2021 08:21:46

Date of unblinding (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 04:02:50 |
| User signature succeeded. | Milton Haber (b) (4) | 03 Apr 2021 05:07:34 |
| User entered '18 Dec 2020' | (b) (4) (b) (4), (b) (6) | 01 Apr 2021 15:20:25 |

US3572330

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

Form: Unblinding

Generated On: 10 Jun 2021 08:21:46

[Participant randomization assignment](#)

| Audit | User | Time (GMT) |
|--------------------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 04:02:50 |
| User signature succeeded. | Milton Haber (b) (4) | 03 Apr 2021 05:07:34 |
| User entered 'mRNA-1273 (mRNA-1273)' | (b) (4) (b) (4), (b) (6) | 01 Apr 2021 15:20:25 |

US3572330

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

Form: Unblinding

Generated On: 10 Jun 2021 08:21:46

[Actual Dose 1](#)

| Audit | User | Time (GMT) |
|--------------------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 04:02:50 |
| User signature succeeded. | Milton Haber (b) (4) | 03 Apr 2021 05:07:34 |
| User entered 'mRNA-1273 (mRNA-1273)' | (b) (4) (b) (4), (b) (6) | 01 Apr 2021 15:20:25 |

US3572330

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

Form: Unblinding

Generated On: 10 Jun 2021 08:21:46

[Actual Dose 2](#)

| Audit | User | Time (GMT) |
|--------------------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 04:02:50 |
| User signature succeeded. | Milton Haber (b) (4) | 03 Apr 2021 05:07:34 |
| User entered 'mRNA-1273 (mRNA-1273)' | (b) (4) (b) (4), (b) (6) | 01 Apr 2021 15:20:25 |

US3572330

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

Form: Unblinding

Generated On: 10 Jun 2021 08:21:46

[Will participant receive mRNA-1273?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 04:02:50 |
| User signature succeeded. | Milton Haber (b) (4) | 03 Apr 2021 05:07:34 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 01 Apr 2021 15:20:25 |

US3572330

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

Form: Unblinding

Generated On: 10 Jun 2021 08:21:46

[Placebo Only Flag](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 01 Apr 2021 15:20:25 |

US3572330

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

Form: Unblinding

Generated On: 10 Jun 2021 08:21:46

[Continuing with mRNA-1273](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 01 Apr 2021 15:20:25 |

US3572330

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:21:46

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 04:03:04 |
| User signature succeeded. | Milton Haber (b) (4) | 03 Apr 2021 05:07:34 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 01 Apr 2021 15:20:28 |

US3572330

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:21:46

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 04:03:04 |
| User signature succeeded. | Milton Haber (b) (4) | 03 Apr 2021 05:07:34 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 01 Apr 2021 15:20:28 |

US3572330

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:21:46

[Collection time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 04:03:04 |
| User signature succeeded. | Milton Haber (b) (4) | 03 Apr 2021 05:07:34 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 01 Apr 2021 15:20:28 |

US3572330

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:21:46

[Collection date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 01 Apr 2021 15:20:28 |

US3572330

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:21:46

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 04:02:59 |
| User signature succeeded. | Milton Haber (b) (4) | 03 Apr 2021 05:07:34 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 01 Apr 2021 15:20:31 |

US3572330

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:21:46

Collection date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 04:02:59 |
| User signature succeeded. | Milton Haber (b) (4) | 03 Apr 2021 05:07:34 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 01 Apr 2021 15:20:31 |

US3572330

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:21:46

[Collection time \(00:00 - 23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 04:02:59 |
| User signature succeeded. | Milton Haber (b) (4) | 03 Apr 2021 05:07:34 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 01 Apr 2021 15:20:31 |

US3572330

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:21:46

[Collection Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 01 Apr 2021 15:20:31 |

US3572330

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 08:21:46

[Did the participant experience any adverse events?](#)

| Audit | User | Time (GMT) |
|---|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 09:15:45 |
| User signature succeeded. | Milton Haber (b) (4) (b) (4) | 13 Apr 2021 04:35:22 |
| User closed query 'Per CDM: In Diary Dose 1, one or more symptoms are present on day 8 after dosing. Solicited adverse reactions lasting beyond 7 days post injection are to be recorded as Adverse Events. Please review and update the Adverse Events accordingly.' (Site from DM). | (u) (4), (b) (6) | 12 Apr 2021 11:36:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 11 Apr 2021 22:24:29 |
| Query 'Per CDM: In Diary Dose 1, one or more symptoms are present on day 8 after dosing. Solicited adverse reactions lasting beyond 7 days post injection are to be recorded as Adverse Events. Please review and update the Adverse Events accordingly.' | (b) (4), (b) (6) | 07 Apr 2021 19:24:16 |
| answered with 'Update' (Site from DM). | | |
| User entered 'Yes (Y)' reason for change: Data Entry Error | (b) (4), (b) (6) | 07 Apr 2021 18:57:34 |
| User opened query 'Per CDM: In Diary Dose 1, one or more symptoms are present on day 8 after dosing. Solicited adverse reactions lasting beyond 7 days post injection are to be recorded as Adverse Events. Please review and update the Adverse Events accordingly.' (Site from DM). | (b) (4), (b) (6) | 31 Mar 2021 22:38:26 |
| User closed query 'Per source, Losartan/HCTZ is noted on the CM log. Please review and reconcile EDC. | (b) (4), (b) (6) | 22 Feb 2021 10:15:04 |
| ' (Site from CRA). | | |
| Query 'Per source, Losartan/HCTZ is noted on the CM log. Please review and reconcile EDC. | (b) (4), (b) (6) | 10 Feb 2021 06:34:52 |
| ' answered with 'no reportable AE's at this time. Losartan listed on CM eCRF for MH of hypertension' (Site from CRA). | | |
| User entered 'No (N)' reason for change: Data Entry Error | (b) (4), (b) (6) | 10 Feb 2021 06:33:33 |
| User opened query 'Per source, Losartan/HCTZ is noted on the CM log. Please review and reconcile EDC. | (b) (4), (b) (6) | 19 Jan 2021 20:39:45 |
| ' (Site from CRA). | | |

US3572330

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 08:21:46

[Did the participant experience any adverse events?](#)

| Audit | User | Time (GMT) |
|------------------------|----------------------------------|----------------------|
| User entered 'Yes (Y)' | Martha Bunnell-Pollak (b) (4) | 28 Sep 2020 20:06:33 |

US3572330

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:21:46

[AEID](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 06:37:17 |

US3572330

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:21:46

[Adverse event](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 06:37:17 |
| DataPoint Verified. | (b) (4), (b) (6) | 11 Apr 2021 22:24:38 |
| User signature succeeded. | Milton Haber (b) (4) | 11 Apr 2021 07:14:23 |
| User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Asthenic conditions, PT: Fatigue, LLT: Fatigue - version MedDRA\23.0. | Coder Import (b) (4) | 07 Apr 2021 19:23:37 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0. | Coder Import (b) (4) | 07 Apr 2021 19:23:37 |
| Data point term sent to Coder | System | 07 Apr 2021 19:23:00 |
| User entered 'Fatigue' | (b) (4), (b) (6) | 07 Apr 2021 19:22:51 |

US3572330

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:21:46

[Was this a medically-attended AE?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 06:37:17 |
| DataPoint Verified. | (b) (4), (b) (6) | 11 Apr 2021 22:24:38 |
| User signature succeeded. | Milton Haber (b) (4) | 11 Apr 2021 07:14:23 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 07 Apr 2021 19:22:51 |

US3572330

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:21:46

[Was this a Solicited Adverse Reaction?](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 06:37:17 |
| User signature succeeded. | Milton Haber (b) (4) | 28 Apr 2021 10:15:36 |
| DataPoint Verified. | (b) (4) (u) (4), (b) (6) | 21 Apr 2021 14:38:03 |
| User closed query 'Per CDM: SAR = No. However, this event was reported in eDiary Dose 1, Day 8. Please review and reconcile, else clarify.' (Site from DM). | (b) (4), (b) (6) | 21 Apr 2021 07:06:30 |
| Query 'Per CDM: SAR = No. However, this event was reported in eDiary Dose 1, Day 8. Please review and reconcile, else clarify.' answered with 'Updated per query resolution' (Site from DM). | (b) (4), (b) (6) | 20 Apr 2021 14:15:40 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 20 Apr 2021 14:15:28 |
| Signature has been broken. | (b) (4), (b) (6) | 20 Apr 2021 14:15:28 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | (b) (4), (b) (6) | 20 Apr 2021 14:15:28 |
| User opened query 'Per CDM: SAR = No. However, this event was reported in eDiary Dose 1, Day 8. Please review and reconcile, else clarify.' (Site from DM). | (b) (4), (b) (6) | 19 Apr 2021 01:12:33 |
| DataPoint Verified. | (b) (4), (b) (6) | 11 Apr 2021 22:24:38 |
| User signature succeeded. | Milton Haber (b) (4) | 11 Apr 2021 07:14:23 |
| User entered 'No (N)' | (b) (4) (u) (4), (b) (6) | 07 Apr 2021 19:22:51 |

US3572330

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:21:46

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 06:37:17 |
| DataPoint Verified. | (b) (4), (b) (6) | 11 Apr 2021 22:24:38 |
| User signature succeeded. | Milton Haber (b) (4) | 11 Apr 2021 07:14:23 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 07 Apr 2021 19:22:51 |

US3572330

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:21:46

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 06:37:17 |
| DataPoint Verified. | (b) (4), (b) (6) | 11 Apr 2021 22:24:38 |
| User signature succeeded. | Milton Haber (b) (4) | 11 Apr 2021 07:14:23 |
| User entered '28 Sep 2020' | (b) (4) (b) (4), (b) (6) | 07 Apr 2021 19:22:51 |

US3572330

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:21:46

[Start time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 06:37:17 |
| DataPoint Verified. | (b) (4), (b) (6) | 11 Apr 2021 22:24:38 |
| User signature succeeded. | Milton Haber (b) (4) | 11 Apr 2021 07:14:23 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 07 Apr 2021 19:22:51 |

US3572330

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:21:46

[AE start date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 06:37:17 |
| User entered empty. | System | 07 Apr 2021 19:22:51 |

US3572330

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:21:46

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 06:37:17 |
| DataPoint Verified. | (b) (4), (b) (6) | 11 Apr 2021 22:24:38 |
| User signature succeeded. | Milton Haber (b) (4) | 11 Apr 2021 07:14:23 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 07 Apr 2021 19:22:51 |

US3572330

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:21:46

If not Ongoing, end date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 06:37:17 |
| DataPoint Verified. | (b) (4), (b) (6) | 11 Apr 2021 22:24:38 |
| User signature succeeded. | Milton Haber (b) (4) | 11 Apr 2021 07:14:23 |
| User entered '3 Nov 2020' | (b) (4) (b) (4), (b) (6) | 07 Apr 2021 19:22:51 |

US3572330

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:21:46

End time (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 06:37:17 |
| DataPoint Verified. | (b) (4), (b) (6) | 11 Apr 2021 22:24:38 |
| User signature succeeded. | Milton Haber (b) (4) | 11 Apr 2021 07:14:23 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 07 Apr 2021 19:22:51 |

US3572330

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:21:46

[AE End Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 06:37:17 |
| User entered empty. | System | 07 Apr 2021 19:22:51 |

US3572330

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:21:46

[Severity](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 06:37:17 |
| DataPoint Verified. | (b) (4), (b) (6) | 11 Apr 2021 22:24:38 |
| User signature succeeded. | Milton Haber (b) (4) | 11 Apr 2021 07:14:23 |
| User entered 'Grade 2/Moderate (Grade 2/Moderate)' | (b) (4) (b) (4), (b) (6) | 07 Apr 2021 19:22:51 |

US3572330

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:21:46

[Is the adverse event serious?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 06:37:17 |
| DataPoint Verified. | (b) (4), (b) (6) | 11 Apr 2021 22:24:38 |
| User signature succeeded. | Milton Haber (b) (4) | 11 Apr 2021 07:14:23 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 07 Apr 2021 19:22:51 |

US3572330

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:21:46

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 06:37:17 |
| DataPoint Verified. | (b) (4), (b) (6) | 11 Apr 2021 22:24:38 |
| User signature succeeded. | Milton Haber (b) (4) | 11 Apr 2021 07:14:23 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 07 Apr 2021 19:22:51 |

US3572330

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:21:46

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 06:37:17 |
| DataPoint Verified. | (b) (4), (b) (6) | 11 Apr 2021 22:24:38 |
| User signature succeeded. | Milton Haber (b) (4) | 11 Apr 2021 07:14:23 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 07 Apr 2021 19:22:51 |

US3572330

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:21:46

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 06:37:17 |
| DataPoint Verified. | (b) (4), (b) (6) | 11 Apr 2021 22:24:38 |
| User signature succeeded. | Milton Haber (b) (4) | 11 Apr 2021 07:14:23 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 07 Apr 2021 19:22:51 |

US3572330

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:21:46

Hospital Admission Date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 06:37:17 |
| DataPoint Verified. | (b) (4), (b) (6) | 11 Apr 2021 22:24:38 |
| User signature succeeded. | Milton Haber (b) (4) | 11 Apr 2021 07:14:23 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 07 Apr 2021 19:22:51 |

US3572330

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:21:46

Hospital Discharge Date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 06:37:17 |
| DataPoint Verified. | (b) (4), (b) (6) | 11 Apr 2021 22:24:38 |
| User signature succeeded. | Milton Haber (b) (4) | 11 Apr 2021 07:14:23 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 07 Apr 2021 19:22:51 |

US3572330

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:21:46

[Admitted to ICU?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 06:37:17 |
| DataPoint Verified. | (b) (4), (b) (6) | 11 Apr 2021 22:24:38 |
| User signature succeeded. | Milton Haber (b) (4) | 11 Apr 2021 07:14:23 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 07 Apr 2021 19:22:51 |

US3572330

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:21:46

[Number of Days in ICU](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 06:37:17 |
| DataPoint Verified. | (b) (4), (b) (6) | 11 Apr 2021 22:24:38 |
| User signature succeeded. | Milton Haber (b) (4) | 11 Apr 2021 07:14:23 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 07 Apr 2021 19:22:51 |

US3572330

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:21:46

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 06:37:17 |
| DataPoint Verified. | (b) (4), (b) (6) | 11 Apr 2021 22:24:38 |
| User signature succeeded. | Milton Haber (b) (4) | 11 Apr 2021 07:14:23 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 07 Apr 2021 19:22:51 |

US3572330

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:21:46

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 06:37:17 |
| DataPoint Verified. | (b) (4), (b) (6) | 11 Apr 2021 22:24:38 |
| User signature succeeded. | Milton Haber (b) (4) | 11 Apr 2021 07:14:23 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 07 Apr 2021 19:22:51 |

US3572330

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:21:46

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 06:37:17 |
| DataPoint Verified. | (b) (4), (b) (6) | 11 Apr 2021 22:24:38 |
| User signature succeeded. | Milton Haber (b) (4) | 11 Apr 2021 07:14:23 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 07 Apr 2021 19:22:51 |

US3572330

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:21:46

[Relationship to investigational product](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 06:37:17 |
| DataPoint Verified. | (b) (4), (b) (6) | 11 Apr 2021 22:24:38 |
| User signature succeeded. | Milton Haber (b) (4) | 11 Apr 2021 07:14:23 |
| User closed query 'Data is required. Please complete.' (Site from System). | System | 07 Apr 2021 19:23:23 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 07 Apr 2021 19:23:23 |
| User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error | (b) (4), (b) (6) | 07 Apr 2021 19:23:23 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 07 Apr 2021 19:22:51 |
| User entered empty. | (b) (4), (b) (6) | 07 Apr 2021 19:22:51 |

US3572330

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:21:46

[Relationship to Study Procedure](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 06:37:17 |
| DataPoint Verified. | (b) (4), (b) (6) | 11 Apr 2021 22:24:38 |
| User signature succeeded. | Milton Haber (b) (4) | 11 Apr 2021 07:14:23 |
| User closed query 'Data is required. Please complete.' (Site from System). | (b) (4) | 07 Apr 2021 19:23:23 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 07 Apr 2021 19:23:23 |
| User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error | (b) (4), (b) (6) | 07 Apr 2021 19:23:23 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 07 Apr 2021 19:22:51 |
| User entered empty. | (b) (4), (b) (6) | 07 Apr 2021 19:22:51 |

US3572330

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:21:46

Action taken with investigational product

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 06:37:17 |
| DataPoint Verified. | (b) (4), (b) (6) | 11 Apr 2021 22:24:38 |
| User signature succeeded. | Milton Haber (b) (4) | 11 Apr 2021 07:14:23 |
| User closed query 'Data is required. Please complete.' (Site from System). | System | 07 Apr 2021 19:23:23 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 07 Apr 2021 19:23:23 |
| User entered 'None (NONE)' reason for change: Data Entry Error | (b) (4), (b) (6) | 07 Apr 2021 19:23:23 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 07 Apr 2021 19:22:51 |
| User entered empty. | (b) (4), (b) (6) | 07 Apr 2021 19:22:51 |

US3572330

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:21:46

None

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 06:37:17 |
| DataPoint Verified. | (b) (4), (b) (6) | 11 Apr 2021 22:24:38 |
| User signature succeeded. | Milton Haber (b) (4) | 11 Apr 2021 07:14:23 |
| User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System). | (b) (4) System | 07 Apr 2021 19:23:23 |
| User entered '1' reason for change: Data Entry Error | (b) (4), (b) (6) | 07 Apr 2021 19:23:23 |
| User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System). | System | 07 Apr 2021 19:22:51 |
| User entered '0' | (b) (4), (b) (6) | 07 Apr 2021 19:22:51 |

US3572330

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:21:46

[Concomitant Medication](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 06:37:17 |
| DataPoint Verified. | (b) (4), (b) (6) | 11 Apr 2021 22:24:38 |
| User signature succeeded. | Milton Haber (b) (4) | 11 Apr 2021 07:14:23 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 07 Apr 2021 19:22:51 |

US3572330

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:21:46

[Concomitant Procedure](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 06:37:17 |
| DataPoint Verified. | (b) (4), (b) (6) | 11 Apr 2021 22:24:38 |
| User signature succeeded. | Milton Haber (b) (4) | 11 Apr 2021 07:14:23 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 07 Apr 2021 19:22:51 |

US3572330

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:21:46

[Outcome](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 06:37:17 |
| DataPoint Verified. | (b) (4), (b) (6) | 11 Apr 2021 22:24:38 |
| User signature succeeded. | Milton Haber (b) (4) | 11 Apr 2021 07:14:23 |
| User closed query 'Data is required. Please complete.' (Site from System). | (b) (4) | 07 Apr 2021 19:23:23 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 07 Apr 2021 19:23:23 |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: | (b) (4), (b) (6) | 07 Apr 2021 19:23:23 |
| Data Entry Error | | |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 07 Apr 2021 19:22:51 |
| User entered empty. | (b) (4), (b) (6) | 07 Apr 2021 19:22:51 |

US3572330

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:21:46

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 06:37:17 |
| DataPoint Verified. | (b) (4), (b) (6) | 11 Apr 2021 22:24:38 |
| User signature succeeded. | Milton Haber (b) (4) | 11 Apr 2021 07:14:23 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 07 Apr 2021 19:22:51 |

US3572330

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:21:46

[Narrative](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 06:37:17 |
| DataPoint Verified. | (b) (4), (b) (6) | 11 Apr 2021 22:24:38 |
| User signature succeeded. | Milton Haber (b) (4) | 11 Apr 2021 07:14:23 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 07 Apr 2021 19:22:51 |

US3572330

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:21:46

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 06:37:17 |
| User entered '0' | System | 07 Apr 2021 19:22:51 |

US3572330

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:21:46

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 06:37:17 |
| User entered '0' | System | 07 Apr 2021 19:22:51 |

US3572330

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:21:46

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 06:37:17 |

US3572330

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:21:46

[AEID](#)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 29 Apr 2021 17:59:06 |
| User signature succeeded. | Milton Haber (b) (4) | 29 Apr 2021 15:47:47 |
| Reviewed for Safety. | (b) (4) (u) (+), (b) (6) | 29 Apr 2021 13:05:29 |
| User entered 'USA-US091-2021-mRNA-1273-P301000021' | System | 29 Apr 2021 13:05:12 |
| User entered 'New' | (b) (4), (b) (6) | 29 Apr 2021 13:05:12 |

US3572330

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:21:46

[Adverse event](#)

| Audit | User | Time (GMT) |
|---|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 29 Apr 2021 17:59:06 |
| User signature succeeded. | Milton Haber (b) (4) | 28 Apr 2021 22:40:42 |
| User coded data point as SOC: Surgical and medical procedures, HLGT: Gastrointestinal therapeutic procedures, HLT: Gastric therapeutic procedures, PT: Gastric bypass, LLT: Gastric bypass - version MedDRA\23.0. | Coder Import (b) (4) | 28 Apr 2021 21:17:53 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0. | Coder Import (b) (4) | 28 Apr 2021 21:17:53 |
| Data point term sent to Coder | System | 28 Apr 2021 20:45:42 |
| User entered 'Elective Gastric Bypass' | Maria Candelario (b) (4) | 28 Apr 2021 20:45:15 |

US3572330

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:21:46

[Was this a medically-attended AE?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 29 Apr 2021 17:59:06 |
| User signature succeeded. | Milton Haber (b) (4) | 28 Apr 2021 22:40:42 |
| User entered 'No (N)' | (b) (4) Maria Candelario (b) (4) | 28 Apr 2021 20:45:15 |

US3572330

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:21:46

[Was this a Solicited Adverse Reaction?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 29 Apr 2021 17:59:06 |
| User signature succeeded. | Milton Haber (b) (4) | 28 Apr 2021 22:40:42 |
| User entered 'No (N)' | (b) (4) Maria Candelario (b) (4) | 28 Apr 2021 20:45:15 |

US3572330

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:21:46

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 29 Apr 2021 17:59:06 |
| User signature succeeded. | Milton Haber (b) (4) | 28 Apr 2021 22:40:42 |
| User entered 'No (N)' | (b) (4) Maria Candelario (b) (4) | 28 Apr 2021 20:45:15 |

US3572330

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:21:46

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

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 29 Apr 2021 17:59:06 |
| User signature succeeded. | Milton Haber (b) (4) | 28 Apr 2021 22:40:42 |
| User entered '16 Jan 2021' | (b) (4) Maria Candelario (b) (4) | 28 Apr 2021 20:45:15 |

US3572330

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:21:46

[Start time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 29 Apr 2021 17:59:06 |
| User signature succeeded. | Milton Haber (b) (4) (b) (4) | 28 Apr 2021 22:40:42 |
| User entered empty. | Maria Candelario (b) (4) (b) (4) | 28 Apr 2021 20:45:15 |

US3572330

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:21:46

[AE start date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 28 Apr 2021 20:45:15 |

US3572330

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:21:46

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 29 Apr 2021 17:59:06 |
| User signature succeeded. | Milton Haber (b) (4) (b) (4) | 28 Apr 2021 22:40:42 |
| User entered 'No (N)' | Maria Candelario (b) (4) (b) (4) | 28 Apr 2021 20:45:15 |

US3572330

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:21:46

If not Ongoing, end date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 29 Apr 2021 17:59:06 |
| User signature succeeded. | Milton Haber (b) (4) | 28 Apr 2021 22:40:42 |
| User entered '18 Jan 2021' | (b) (4) Maria Candelario (b) (4) | 28 Apr 2021 20:45:15 |

US3572330

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:21:46

End time (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 29 Apr 2021 17:59:06 |
| User signature succeeded. | Milton Haber (b) (4) | 28 Apr 2021 22:40:42 |
| User entered empty. | (b) (4) | |
| | Maria Candelario (b) (4) | 28 Apr 2021 20:45:15 |
| | (b) (4) | |

US3572330

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:21:46

[AE End Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 28 Apr 2021 20:45:15 |

US3572330

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:21:46

[Severity](#)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 29 Apr 2021 17:59:06 |
| User signature succeeded. | Milton Haber (b) (4) | 28 Apr 2021 22:40:42 |
| 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 | 28 Apr 2021 21:33:23 |
| User entered 'Grade 1/Mild (Grade 1/Mild)' reason for change: Data Entry Error | System | 28 Apr 2021 21:33:23 |
| User opened query 'Data is required. Please complete.' (Site from System). | (b) (4), (b) (6) | 28 Apr 2021 21:33:23 |
| User entered empty. | System | 28 Apr 2021 20:45:15 |
| | Maria Candelario (b) (4) | 28 Apr 2021 20:45:15 |
| | (b) (4) | |

US3572330

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:21:46

[Is the adverse event serious?](#)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 29 Apr 2021 17:59:06 |
| User signature succeeded. | Milton Haber (b) (4) | 28 Apr 2021 22:40:42 |
| User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System). | System | 28 Apr 2021 20:47:54 |
| User closed query 'Data is required. Please complete.' (Site from System). | System | 28 Apr 2021 20:46:01 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 28 Apr 2021 20:46:01 |
| User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System). | System | 28 Apr 2021 20:46:01 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | Maria Candelario (b) (4) | 28 Apr 2021 20:46:01 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 28 Apr 2021 20:45:15 |
| User entered empty. | Maria Candelario (b) (4) | 28 Apr 2021 20:45:15 |

US3572330

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:21:46

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 29 Apr 2021 17:59:06 |
| User signature succeeded. | Milton Haber (b) (4) (b) (4) | 28 Apr 2021 22:40:42 |
| User entered '0' | Maria Candelario (b) (4) (b) (4) | 28 Apr 2021 20:45:15 |

US3572330

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:21:46

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 29 Apr 2021 17:59:06 |
| User signature succeeded. | Milton Haber (b) (4) (b) (4) | 28 Apr 2021 22:40:42 |
| User entered '0' | Maria Candelario (b) (4) (b) (4) | 28 Apr 2021 20:45:15 |

US3572330

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:21:46

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 29 Apr 2021 17:59:06 |
| User signature succeeded. | Milton Haber (b) (4) | 28 Apr 2021 22:40:42 |
| User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System). | System | 28 Apr 2021 21:32:56 |
| Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered by data change (Site from System). | System | 28 Apr 2021 21:32:56 |
| User closed query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System). | System | 28 Apr 2021 20:47:54 |
| Query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System). | System | 28 Apr 2021 20:47:54 |
| User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System). | System | 28 Apr 2021 20:47:54 |
| User entered '1' reason for change: Data Entry Error | Maria Candelario (b) (4) | 28 Apr 2021 20:47:54 |
| User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System). | System | 28 Apr 2021 20:45:15 |
| User entered '0' | Maria Candelario (b) (4) | 28 Apr 2021 20:45:15 |

US3572330

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:21:46

Hospital Admission Date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 29 Apr 2021 17:59:06 |
| User signature succeeded. | Milton Haber (b) (4) | 28 Apr 2021 22:40:42 |
| User entered '16 Jan 2021' | (b) (4) Maria Candelario (b) (4) | 28 Apr 2021 20:45:15 |

US3572330

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:21:46

Hospital Discharge Date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 29 Apr 2021 17:59:06 |
| User signature succeeded. | Milton Haber (b) (4) | 28 Apr 2021 22:40:42 |
| User entered '18 Jan 2021' | (b) (4) Maria Candelario (b) (4) | 28 Apr 2021 20:45:15 |

US3572330

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:21:46

[Admitted to ICU?](#)

| Audit | User | Time (GMT) |
|---|--------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 29 Apr 2021 17:59:06 |
| User signature succeeded. | Milton Haber (b) (4) | 28 Apr 2021 22:40:42 |
| User entered 'No (N)' reason for change: Data Entry Error | (b) (4) | |
| | (b) (4), (b) (6) | 28 Apr 2021 21:32:56 |
| User entered empty. | Maria Candelario (b) (4) | 28 Apr 2021 20:45:15 |
| | (b) (4) | |

US3572330

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:21:46

[Number of Days in ICU](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 29 Apr 2021 17:59:06 |
| User signature succeeded. | Milton Haber (b) (4) (b) (4) | 28 Apr 2021 22:40:42 |
| User entered empty. | Maria Candelario (b) (4) (b) (4) | 28 Apr 2021 20:45:15 |

US3572330

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:21:46

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 29 Apr 2021 17:59:06 |
| User signature succeeded. | Milton Haber (b) (4) | 28 Apr 2021 22:40:42 |
| User entered '0' | (b) (4) Maria Candelario (b) (4) (b) (4) | 28 Apr 2021 20:45:15 |

US3572330

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:21:46

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 29 Apr 2021 17:59:06 |
| User signature succeeded. | Milton Haber (b) (4) | 28 Apr 2021 22:40:42 |
| User entered '0' | (b) (4) Maria Candelario (b) (4) | 28 Apr 2021 20:45:15 |

US3572330

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:21:46

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 29 Apr 2021 17:59:06 |
| User signature succeeded. | Milton Haber (b) (4) (b) (4) | 28 Apr 2021 22:40:42 |
| User entered '0' | Maria Candelario (b) (4) (b) (4) | 28 Apr 2021 20:45:15 |

US3572330

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:21:46

[Relationship to investigational product](#)

| Audit | User | Time (GMT) |
|--|-------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 29 Apr 2021 17:59:06 |
| User signature succeeded. | Milton Haber (b) (4) (b) (4) | 28 Apr 2021 22:40:42 |
| User entered 'Not Related (NOT RELATED)' | Maria Candelario (b) (4) (b) (4) | 28 Apr 2021 20:45:15 |

US3572330

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:21:46

[Relationship to Study Procedure](#)

| Audit | User | Time (GMT) |
|--|-------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 29 Apr 2021 17:59:06 |
| User signature succeeded. | Milton Haber (b) (4) (b) (4) | 28 Apr 2021 22:40:42 |
| User entered 'Not Related (NOT RELATED)' | Maria Candelario (b) (4) (b) (4) | 28 Apr 2021 20:45:15 |

US3572330

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:21:46

[Action taken with investigational product](#)

| Audit | User | Time (GMT) |
|--|-------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 29 Apr 2021 17:59:06 |
| User signature succeeded. | Milton Haber (b) (4) (b) (4) | 28 Apr 2021 22:40:42 |
| User entered 'Not Applicable (NOT APPLICABLE)' | Maria Candelario (b) (4) (b) (4) | 28 Apr 2021 20:45:15 |

US3572330

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:21:46

[None](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 29 Apr 2021 17:59:06 |
| User signature succeeded. | Milton Haber (b) (4) (b) (4) | 28 Apr 2021 22:40:42 |
| User entered 'l' | Maria Candelario (b) (4) (b) (4) | 28 Apr 2021 20:45:15 |

US3572330

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:21:46

[Concomitant Medication](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 29 Apr 2021 17:59:06 |
| User signature succeeded. | Milton Haber (b) (4) (b) (4) | 28 Apr 2021 22:40:42 |
| User entered '0' | Maria Candelario (b) (4) (b) (4) | 28 Apr 2021 20:45:15 |

US3572330

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:21:46

[Concomitant Procedure](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 29 Apr 2021 17:59:06 |
| User signature succeeded. | Milton Haber (b) (4) | 28 Apr 2021 22:40:42 |
| User entered '0' | (b) (4) Maria Candelario (b) (4) | 28 Apr 2021 20:45:15 |

US3572330

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:21:46

[Outcome](#)

| Audit | User | Time (GMT) |
|---|-------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 29 Apr 2021 17:59:06 |
| User signature succeeded. | Milton Haber (b) (4) (b) (4) | 28 Apr 2021 22:40:42 |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' | Maria Candelario (b) (4) (b) (4) | 28 Apr 2021 20:45:15 |

US3572330

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:21:46

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 29 Apr 2021 17:59:06 |
| User signature succeeded. | Milton Haber (b) (4) | 28 Apr 2021 22:40:42 |
| User entered empty. | (b) (4) Maria Candelario (b) (4) | 28 Apr 2021 20:45:15 |

US3572330

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:21:46

[Narrative](#)

| Audit | User | Time (GMT) |
|--|-------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 29 Apr 2021 17:59:06 |
| User signature succeeded. | Milton Haber (b) (4) (b) (4) | 28 Apr 2021 22:40:42 |
| User entered 'Subject reported having gastric bypass on 16Jan2021, discharged from hospital 18Jan2021. Unable to obtain records, surgery performed in Monterrey Mexico.' | Maria Candelario (b) (4) (b) (4) | 28 Apr 2021 20:45:15 |

US3572330

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:21:46

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'l' | System | 28 Apr 2021 20:46:01 |

US3572330

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:21:46

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '0' | System | 28 Apr 2021 20:45:15 |

US3572330

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:21:46

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '0' | System | 28 Apr 2021 21:32:56 |

US3572330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 08:21:46

[Were any prior/concomitant medications and/or vaccinations taken?](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 09:15:45 |
| DataPoint Verified. | (b) (4), (b) (6) | 11 Apr 2021 22:24:52 |
| User signature succeeded. | Milton Haber (b) (4) | 03 Apr 2021 05:07:34 |
| User entered 'Yes (Y)' | (b) (4) Martha Bunnell-Pollak (b) (4) | 26 Jan 2021 18:49:57 |

US3572330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:21:46

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 13:05:31 |
| DataPoint Verified. | (b) (4), (b) (6) | 11 Apr 2021 22:25:02 |
| User signature succeeded. | Milton Haber (b) (4) | 03 Apr 2021 05:07:34 |
| User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, PRODUCT: ANTIBIOTICS - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 04 Mar 2021 22:27:40 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 04 Mar 2021 22:27:40 |
| Data point term sent to Coder | System | 26 Feb 2021 06:34:52 |
| Coding entries removed. | (b) (4), (b) (6) | 26 Feb 2021 06:34:02 |
| User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, PRODUCT: ANTIBIOTICS - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 26 Jan 2021 23:58:11 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 26 Jan 2021 23:58:11 |
| Data point term sent to Coder | System | 26 Jan 2021 18:51:03 |
| User entered 'Antibiotic (Mexican Drug)' | Martha Bunnell-Pollak (b) (4) | 26 Jan 2021 18:50:59 |

US3572330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:21:46

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 13:05:31 |
| DataPoint Verified. | (b) (4), (b) (6) | 11 Apr 2021 22:25:02 |
| User signature succeeded. | Milton Haber (b) (4) | 03 Apr 2021 05:07:34 |
| User entered 'Yes (Y)' | (b) (4) Martha Bunnell-Pollak (b) (4) | 26 Jan 2021 18:50:59 |

US3572330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:21:46

[Indication](#)

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 13:05:31 |
| DataPoint Verified. | (b) (4), (b) (6) | 11 Apr 2021 22:25:02 |
| User signature succeeded. | Milton Haber (b) (4) | 03 Apr 2021 05:07:34 |
| User closed query 'Per DM CLR: Please update the indication of this medication to include the medical condition being prevented (e.g. prophylaxis for/pre op for). Update Con Med eCRF as appropriate. ' (Site from DM). | (b) (4) (b) (4), (b) (6) | 01 Mar 2021 05:40:34 |
| Query 'Per DM CLR: Please update the indication of this medication to include the medical condition being prevented (e.g. prophylaxis for/pre op for). Update Con Med eCRF as appropriate. ' answered with 'updated' (Site from DM). | (b) (4), (b) (6) | 26 Feb 2021 06:38:27 |
| User entered 'prophylaxis pre-op for gastric bypass surgery' reason for change: Data Entry Error | (b) (4), (b) (6) | 26 Feb 2021 06:34:02 |
| User opened query 'Per DM CLR: Please update the indication of this medication to include the medical condition being prevented (e.g. prophylaxis for/pre op for). Update Con Med eCRF as appropriate. ' (Site from DM). | (b) (4), (b) (6) | 23 Feb 2021 00:26:46 |
| User entered 'Pre Op' | Martha Bunnell-Pollak (b) (4) | 26 Jan 2021 18:50:59 |

US3572330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:21:46

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 13:05:31 |
| DataPoint Verified. | (b) (4), (b) (6) | 11 Apr 2021 22:25:02 |
| User signature succeeded. | Milton Haber (b) (4) | 03 Apr 2021 05:07:34 |
| User entered 'l' | (b) (4) Martha Bunnell-Pollak (b) (4) | 26 Jan 2021 18:50:59 |

US3572330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:21:46

[Dose unit](#)

| Audit | User | Time (GMT) |
|--------------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 13:05:31 |
| DataPoint Verified. | (b) (4), (b) (6) | 11 Apr 2021 22:25:02 |
| User signature succeeded. | Milton Haber (b) (4) | 03 Apr 2021 05:07:34 |
| User entered 'tablet (TABLET)' | (b) (4) Martha Bunnell-Pollak (b) (4) | 26 Jan 2021 18:50:59 |

US3572330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:21:46

[If dose unit is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 13:05:31 |
| DataPoint Verified. | (b) (4), (b) (6) | 11 Apr 2021 22:25:02 |
| User signature succeeded. | Milton Haber (b) (4) | 03 Apr 2021 05:07:34 |
| User entered empty. | (b) (4) Martha Bunnell-Pollak (b) (4) | 26 Jan 2021 18:50:59 |

US3572330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:21:46

[Frequency](#)

| Audit | User | Time (GMT) |
|----------------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 13:05:31 |
| DataPoint Verified. | (b) (4), (b) (6) | 11 Apr 2021 22:25:02 |
| User signature succeeded. | Milton Haber (b) (4) | 03 Apr 2021 05:07:34 |
| User entered 'twice daily (BID)' | (b) (4) Martha Bunnell-Pollak (b) (4) | 26 Jan 2021 18:50:59 |

US3572330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:21:46

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 13:05:31 |
| DataPoint Verified. | (b) (4), (b) (6) | 11 Apr 2021 22:25:02 |
| User signature succeeded. | Milton Haber (b) (4) | 03 Apr 2021 05:07:34 |
| User entered empty. | (b) (4) Martha Bunnell-Pollak (b) (4) | 26 Jan 2021 18:50:59 |

US3572330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:21:46

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 13:05:31 |
| DataPoint Verified. | (b) (4), (b) (6) | 11 Apr 2021 22:25:02 |
| User signature succeeded. | Milton Haber (b) (4) | 03 Apr 2021 05:07:34 |
| User entered 'Oral (ORAL)' | (b) (4) Martha Bunnell-Pollak (b) (4) | 26 Jan 2021 18:50:59 |

US3572330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:21:46

[If route of administration is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 13:05:31 |
| DataPoint Verified. | (b) (4), (b) (6) | 11 Apr 2021 22:25:02 |
| User signature succeeded. | Milton Haber (b) (4) | 03 Apr 2021 05:07:34 |
| User entered empty. | (b) (4) Martha Bunnell-Pollak (b) (4) | 26 Jan 2021 18:50:59 |

US3572330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:21:46

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

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 13:05:31 |
| DataPoint Verified. | (b) (4), (b) (6) | 11 Apr 2021 22:25:02 |
| User signature succeeded. | Milton Haber (b) (4) | 03 Apr 2021 05:07:34 |
| User entered '15 Jan 2021' | (b) (4) Martha Bunnell-Pollak (b) (4) | 26 Jan 2021 18:50:59 |

US3572330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:21:46

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 13:05:31 |
| DataPoint Verified. | (b) (4), (b) (6) | 11 Apr 2021 22:25:02 |
| User signature succeeded. | Milton Haber (b) (4) | 03 Apr 2021 05:07:34 |
| User entered '0' | (b) (4) Martha Bunnell-Pollak (b) (4) | 26 Jan 2021 18:50:59 |

US3572330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:21:46

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 13:05:31 |
| DataPoint Verified. | (b) (4), (b) (6) | 11 Apr 2021 22:25:02 |
| User signature succeeded. | Milton Haber (b) (4) | 03 Apr 2021 05:07:34 |
| User entered 'No (N)' | (b) (4) Martha Bunnell-Pollak (b) (4) | 26 Jan 2021 18:50:59 |

US3572330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:21:46

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 13:05:31 |
| DataPoint Verified. | (b) (4), (b) (6) | 11 Apr 2021 22:25:02 |
| User signature succeeded. | Milton Haber (b) (4) | 03 Apr 2021 05:07:34 |
| User entered '17 Jan 2021' | (b) (4) Martha Bunnell-Pollak (b) (4) | 26 Jan 2021 18:50:59 |

US3572330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:21:46

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 13:05:31 |
| DataPoint Verified. | (b) (4), (b) (6) | 11 Apr 2021 22:25:02 |
| User signature succeeded. | Milton Haber (b) (4) | 03 Apr 2021 05:07:34 |
| User entered 'No (N)' | (b) (4) Martha Bunnell-Pollak (b) (4) | 26 Jan 2021 18:50:59 |

US3572330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:21:46

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 13:05:31 |
| User entered '2' | System | 26 Jan 2021 18:50:59 |

US3572330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:21:46

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 13:05:31 |
| User entered 'I' | System | 26 Jan 2021 18:50:59 |

US3572330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:21:46

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 13:05:31 |
| User entered '804 (804)' | System | 26 Jan 2021 18:50:59 |

US3572330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:21:46

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 11 Apr 2021 22:25:02 |
| User signature succeeded. | Milton Haber (b) (4) | 03 Apr 2021 05:07:34 |
| User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, PRODUCT: LOSARTAN - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 03 Feb 2021 17:48:36 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 03 Feb 2021 17:48:36 |
| Data point term sent to Coder | System | 03 Feb 2021 17:47:54 |
| User entered 'LOSARTAN' | (b) (4), (b) (6) | 03 Feb 2021 17:47:04 |

US3572330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:21:46

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 11 Apr 2021 22:25:02 |
| User signature succeeded. | Milton Haber (b) (4) | 03 Apr 2021 05:07:34 |
| User entered 'No (N)' | (b) (4) (u) (4), (b) (6) | 03 Feb 2021 17:47:04 |

US3572330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:21:46

[Indication](#)

| Audit | User | Time (GMT) |
|-----------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 11 Apr 2021 22:25:02 |
| User signature succeeded. | Milton Haber (b) (4) | 03 Apr 2021 05:07:34 |
| User entered 'HYPERTENSION' | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 17:47:04 |

US3572330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:21:46

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 11 Apr 2021 22:25:02 |
| User signature succeeded. | Milton Haber (b) (4) | 03 Apr 2021 05:07:34 |
| User entered '50/25' | (b) (4) (u) (4), (b) (6) | 03 Feb 2021 17:47:04 |

US3572330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:21:46

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 11 Apr 2021 22:25:02 |
| User signature succeeded. | Milton Haber (b) (4) | 03 Apr 2021 05:07:34 |
| User entered 'mg (mg)' | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 17:47:04 |

US3572330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:21:46

[If dose unit is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 11 Apr 2021 22:25:02 |
| User signature succeeded. | Milton Haber (b) (4) | 03 Apr 2021 05:07:34 |
| User entered empty. | (b) (4) (u) (4), (b) (6) | 03 Feb 2021 17:47:04 |

US3572330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:21:46

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 11 Apr 2021 22:25:02 |
| User signature succeeded. | Milton Haber (b) (4) | 03 Apr 2021 05:07:34 |
| User entered 'once daily (QD)' | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 17:47:04 |

US3572330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:21:46

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 11 Apr 2021 22:25:02 |
| User signature succeeded. | Milton Haber (b) (4) | 03 Apr 2021 05:07:34 |
| User entered empty. | (b) (4) (u) (4), (b) (6) | 03 Feb 2021 17:47:04 |

US3572330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:21:46

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 11 Apr 2021 22:25:02 |
| User signature succeeded. | Milton Haber (b) (4) | 03 Apr 2021 05:07:34 |
| User entered 'Oral (ORAL)' | (b) (4) (u) (4), (b) (6) | 03 Feb 2021 17:47:04 |

US3572330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:21:46

[If route of administration is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 11 Apr 2021 22:25:02 |
| User signature succeeded. | Milton Haber (b) (4) | 03 Apr 2021 05:07:34 |
| User entered empty. | (b) (4) (u) (4), (b) (6) | 03 Feb 2021 17:47:04 |

US3572330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:21:46

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 11 Apr 2021 22:25:02 |
| User signature succeeded. | Milton Haber (b) (4) | 03 Apr 2021 05:07:34 |
| User entered '01 Jan 2019' | (b) (4) (b) (4), (b) (6) | 03 Feb 2021 17:47:04 |

US3572330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:21:46

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 11 Apr 2021 22:25:02 |
| User signature succeeded. | Milton Haber (b) (4) | 03 Apr 2021 05:07:34 |
| User entered '0' | (b) (4) (u) (4), (b) (6) | 03 Feb 2021 17:47:04 |

US3572330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:21:46

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 11 Apr 2021 22:25:02 |
| User signature succeeded. | Milton Haber (b) (4) | 03 Apr 2021 05:07:34 |
| User entered 'Yes (Y)' | (b) (4) (u) (4), (b) (6) | 03 Feb 2021 17:47:04 |

US3572330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:21:46

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 11 Apr 2021 22:25:02 |
| User signature succeeded. | Milton Haber (b) (4) | 03 Apr 2021 05:07:34 |
| User entered empty. | (b) (4) (u) (4), (b) (6) | 03 Feb 2021 17:47:04 |

US3572330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:21:46

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 11 Apr 2021 22:25:02 |
| User signature succeeded. | Milton Haber (b) (4) | 03 Apr 2021 05:07:34 |
| User entered 'No (N)' | (b) (4) (u) (4), (b) (6) | 03 Feb 2021 17:47:04 |

US3572330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:21:46

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'l' | System | 03 Feb 2021 17:47:04 |

US3572330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:21:46

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 03 Feb 2021 17:47:04 |

US3572330

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:21:46

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 03 Feb 2021 17:47:04 |

US3572330

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 08:21:46

[Were any concomitant procedures performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 09:15:45 |
| DataPoint Verified. | (b) (4), (b) (6) | 11 Apr 2021 22:25:13 |
| User signature succeeded. | Milton Haber (b) (4) | 03 Apr 2021 05:07:34 |
| User entered 'Yes (Y)' | (b) (4) Martha Bunnell-Pollak (b) (4) | 26 Jan 2021 18:49:26 |

US3572330

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:21:46

Procedure/Surgery date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 11 Apr 2021 22:25:24 |
| User signature succeeded. | Milton Haber (b) (4) | 03 Apr 2021 05:07:34 |
| User entered '16 Jan 2021' | (b) (4) Martha Bunnell-Pollak (b) (4) | 26 Jan 2021 18:49:50 |

US3572330

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:21:46

[Procedure/Surgery](#)

| Audit | User | Time (GMT) |
|-------------------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 11 Apr 2021 22:25:24 |
| User signature succeeded. | Milton Haber (b) (4) (b) (4) | 03 Apr 2021 05:07:34 |
| User entered 'Gastric Bypass' | Martha Bunnell-Pollak (b) (4) | 26 Jan 2021 18:49:50 |

US3572330

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:21:46

[Indication](#)

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 11 Apr 2021 22:25:24 |
| User signature succeeded. | Milton Haber (b) (4) | 03 Apr 2021 05:07:34 |
| User closed query 'Per DM CLR: Indication = Medical History, however, there is no corresponding medical condition recorded for this procedure in the MedHistory eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify. ' (Site from DM). | (b) (4) (u) (4), (b) (6) | 02 Mar 2021 07:12:22 |
| Query 'Per DM CLR: Indication = Medical History, however, there is no corresponding medical condition recorded for this procedure in the MedHistory eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify. ' answered with 'updated/clarified' (Site from DM). | (b) (4), (b) (6) | 26 Feb 2021 06:38:02 |
| User entered 'Other (OTHER)' reason for change: Data Entry Error | (b) (4), (b) (6) | 26 Feb 2021 06:37:39 |
| User opened query 'Per DM CLR: Indication = Medical History, however, there is no corresponding medical condition recorded for this procedure in the MedHistory eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify. ' (Site from DM). | (b) (4), (b) (6) | 25 Feb 2021 10:02:11 |
| User entered 'Medical History (MH)' | Martha Bunnell-Pollak (b) (4) | 26 Jan 2021 18:49:50 |

US3572330

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:21:46

If indication is Other, specify

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 11 Apr 2021 22:25:24 |
| User signature succeeded. | Milton Haber (b) (4) | 03 Apr 2021 05:07:34 |
| User entered 'weight reduction' reason for change: Data Entry Error | (b) (4) | 26 Feb 2021 06:37:39 |
| User entered empty. | (b) (4), (b) (6) | 26 Feb 2021 06:37:39 |
| | Martha Bunnell-Pollak | 26 Jan 2021 18:49:50 |
| | (b) (4) | |

US3572330

Folder: SAE USA-US091-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 10 Jun 2021 08:21:46

[SAEID](#)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 30 Apr 2021 14:41:04 |
| User signature succeeded. | Milton Haber (b) (4) | 29 Apr 2021 15:47:47 |
| Reviewed for Safety. | (b) (4) (u) (+), (b) (6) | 29 Apr 2021 13:05:54 |
| User entered 'USA-US091-2021-MRNA-1273-P301000021' | System | 29 Apr 2021 13:05:12 |

US3572330

Folder: SAE USA-US091-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 10 Jun 2021 08:21:46

Serious

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 30 Apr 2021 14:41:04 |
| User signature succeeded. | Milton Haber (b) (4) | 29 Apr 2021 15:47:47 |
| Reviewed for Safety. | (b) (4) (u) (4), (b) (6) | 29 Apr 2021 13:05:54 |
| User entered 'Yes (Y)' | System | 29 Apr 2021 13:05:12 |

US3572330

Folder: SAE USA-US091-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 10 Jun 2021 08:21:46

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 30 Apr 2021 14:41:04 |
| User signature succeeded. | Milton Haber (b) (4) | 29 Apr 2021 15:47:47 |
| Reviewed for Safety. | (b) (4) (u) (4), (b) (6) | 29 Apr 2021 13:05:54 |
| User entered 'No (N)' | System | 29 Apr 2021 13:05:12 |

US3572330

Folder: SAE USA-US091-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 10 Jun 2021 08:21:46

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 30 Apr 2021 14:41:04 |
| User signature succeeded. | Milton Haber (b) (4) | 29 Apr 2021 15:47:47 |
| Reviewed for Safety. | (b) (4) (u) (4), (b) (6) | 29 Apr 2021 13:05:54 |
| User entered 'No (N)' | System | 29 Apr 2021 13:05:12 |

US3572330

Folder: SAE USA-US091-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 10 Jun 2021 08:21:46

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 30 Apr 2021 14:41:04 |
| User signature succeeded. | Milton Haber (b) (4) | 29 Apr 2021 15:47:47 |
| Reviewed for Safety. | (b) (4) (u) (4), (b) (6) | 29 Apr 2021 13:05:54 |
| User entered 'Yes (Y)' | System | 29 Apr 2021 13:05:12 |

US3572330

Folder: SAE USA-US091-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 10 Jun 2021 08:21:46

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 30 Apr 2021 14:41:04 |
| User signature succeeded. | Milton Haber (b) (4) | 29 Apr 2021 15:47:47 |
| Reviewed for Safety. | (b) (4) (u) (4), (b) (6) | 29 Apr 2021 13:05:54 |
| User entered 'No (N)' | System | 29 Apr 2021 13:05:12 |

US3572330

Folder: SAE USA-US091-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 10 Jun 2021 08:21:46

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 30 Apr 2021 14:41:04 |
| User signature succeeded. | Milton Haber (b) (4) | 29 Apr 2021 15:47:47 |
| Reviewed for Safety. | (b) (4) (u) (4), (b) (6) | 29 Apr 2021 13:05:54 |
| User entered 'No (N)' | System | 29 Apr 2021 13:05:12 |

US3572330

Folder: SAE USA-US091-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 10 Jun 2021 08:21:46

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 30 Apr 2021 14:41:04 |
| User signature succeeded. | Milton Haber (b) (4) | 29 Apr 2021 15:47:47 |
| Reviewed for Safety. | (b) (4) (u) (4), (b) (6) | 29 Apr 2021 13:05:54 |
| User entered 'No (N)' | System | 29 Apr 2021 13:05:12 |

US3572330

Folder: SAE USA-US091-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 10 Jun 2021 08:21:46

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 30 Apr 2021 14:41:04 |
| User signature succeeded. | Milton Haber (b) (4) | 29 Apr 2021 15:47:47 |
| Reviewed for Safety. | (b) (4) (u) (4), (b) (6) | 29 Apr 2021 13:05:54 |
| User entered 'Milton' | System | 29 Apr 2021 13:05:12 |

US3572330

Folder: SAE USA-US091-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 10 Jun 2021 08:21:46

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 30 Apr 2021 14:41:04 |
| User signature succeeded. | Milton Haber (b) (4) | 29 Apr 2021 15:47:47 |
| Reviewed for Safety. | (b) (4) (u) (4), (b) (6) | 29 Apr 2021 13:05:54 |
| User entered 'Haber' | System | 29 Apr 2021 13:05:12 |

US3572330

Folder: SAE USA-US091-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 10 Jun 2021 08:21:46

[Site Address: Street](#)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 30 Apr 2021 14:41:04 |
| User signature succeeded. | Milton Haber (b) (4) | 29 Apr 2021 15:47:47 |
| Reviewed for Safety. | (b) (4) (u) (4), (b) (6) | 29 Apr 2021 13:05:54 |
| User entered '2344 Laguna Del Mar, Suite 201' | System | 29 Apr 2021 13:05:12 |

US3572330

Folder: SAE USA-US091-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 10 Jun 2021 08:21:46

[Site Address: City](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 30 Apr 2021 14:41:04 |
| User signature succeeded. | Milton Haber (b) (4) | 29 Apr 2021 15:47:47 |
| Reviewed for Safety. | (b) (4) (u) (4), (b) (6) | 29 Apr 2021 13:05:54 |
| User entered 'Laredo' | System | 29 Apr 2021 13:05:12 |

US3572330

Folder: SAE USA-US091-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 10 Jun 2021 08:21:46

[Site Address: State](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 30 Apr 2021 14:41:04 |
| User signature succeeded. | Milton Haber (b) (4) | 29 Apr 2021 15:47:47 |
| Reviewed for Safety. | (b) (4) (u) (4), (b) (6) | 29 Apr 2021 13:05:54 |
| User entered 'TX' | System | 29 Apr 2021 13:05:12 |

US3572330

Folder: SAE USA-US091-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 10 Jun 2021 08:21:46

[Site Address: Postal Code](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 30 Apr 2021 14:41:04 |
| User signature succeeded. | Milton Haber (b) (4) | 29 Apr 2021 15:47:47 |
| Reviewed for Safety. | (b) (4) (u) (4), (b) (6) | 29 Apr 2021 13:05:54 |
| User entered '78041' | System | 29 Apr 2021 13:05:12 |

US3572330

Folder: SAE USA-US091-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 10 Jun 2021 08:21:46

[Investigator Country](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 30 Apr 2021 14:41:04 |
| User signature succeeded. | Milton Haber (b) (4) | 29 Apr 2021 15:47:47 |
| User entered 'US' | (b) (4) System | 29 Apr 2021 13:06:50 |

US3572330

Folder: SAE USA-US091-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 10 Jun 2021 08:21:46

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 29 Apr 2021 13:06:50 |

US3572330

Folder: SAE USA-US091-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 10 Jun 2021 08:21:46

[SAEID](#)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 30 Apr 2021 14:41:04 |
| User signature succeeded. | Milton Haber (b) (4) | 29 Apr 2021 15:47:47 |
| Reviewed for Safety. | (b) (4) (u) (4), (b) (6) | 29 Apr 2021 13:05:54 |
| User entered 'USA-US091-2021-MRNA-1273-P301000021' | System | 29 Apr 2021 13:05:12 |

US3572330

Folder: SAE USA-US091-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 10 Jun 2021 08:21:46

Serious

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 30 Apr 2021 14:41:04 |
| User signature succeeded. | Milton Haber (b) (4) | 29 Apr 2021 15:47:47 |
| Reviewed for Safety. | (b) (4) (u) (4), (b) (6) | 29 Apr 2021 13:05:54 |
| User entered 'Yes (Y)' | System | 29 Apr 2021 13:05:12 |

US3572330

Folder: SAE USA-US091-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 10 Jun 2021 08:21:46

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 30 Apr 2021 14:41:04 |
| User signature succeeded. | Milton Haber (b) (4) | 29 Apr 2021 15:47:47 |
| Reviewed for Safety. | (b) (4) (u) (4), (b) (6) | 29 Apr 2021 13:05:54 |
| User entered 'No (N)' | System | 29 Apr 2021 13:05:12 |

US3572330

Folder: SAE USA-US091-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 10 Jun 2021 08:21:46

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 30 Apr 2021 14:41:04 |
| User signature succeeded. | Milton Haber (b) (4) | 29 Apr 2021 15:47:47 |
| Reviewed for Safety. | (b) (4) (u) (4), (b) (6) | 29 Apr 2021 13:05:54 |
| User entered 'No (N)' | System | 29 Apr 2021 13:05:12 |

US3572330

Folder: SAE USA-US091-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 10 Jun 2021 08:21:46

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 30 Apr 2021 14:41:04 |
| User signature succeeded. | Milton Haber (b) (4) | 29 Apr 2021 15:47:47 |
| Reviewed for Safety. | (b) (4) (u) (4), (b) (6) | 29 Apr 2021 13:05:54 |
| User entered 'Yes (Y)' | System | 29 Apr 2021 13:05:12 |

US3572330

Folder: SAE USA-US091-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 10 Jun 2021 08:21:46

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 30 Apr 2021 14:41:04 |
| User signature succeeded. | Milton Haber (b) (4) | 29 Apr 2021 15:47:47 |
| Reviewed for Safety. | (b) (4) (u) (4), (b) (6) | 29 Apr 2021 13:05:54 |
| User entered 'No (N)' | System | 29 Apr 2021 13:05:12 |

US3572330

Folder: SAE USA-US091-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 10 Jun 2021 08:21:46

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 30 Apr 2021 14:41:04 |
| User signature succeeded. | Milton Haber (b) (4) | 29 Apr 2021 15:47:47 |
| Reviewed for Safety. | (b) (4) (u) (4), (b) (6) | 29 Apr 2021 13:05:54 |
| User entered 'No (N)' | System | 29 Apr 2021 13:05:12 |

US3572330

Folder: SAE USA-US091-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 10 Jun 2021 08:21:46

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 30 Apr 2021 14:41:04 |
| User signature succeeded. | Milton Haber (b) (4) | 29 Apr 2021 15:47:47 |
| Reviewed for Safety. | (b) (4) (u) (4), (b) (6) | 29 Apr 2021 13:05:54 |
| User entered 'No (N)' | System | 29 Apr 2021 13:05:12 |

US3572330

Folder: SAE USA-US091-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 10 Jun 2021 08:21:46

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 30 Apr 2021 14:41:04 |
| User signature succeeded. | Milton Haber (b) (4) | 29 Apr 2021 15:47:47 |
| Reviewed for Safety. | (b) (4) (u) (4), (b) (6) | 29 Apr 2021 13:05:54 |
| User entered 'Milton' | System | 29 Apr 2021 13:05:12 |

US3572330

Folder: SAE USA-US091-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 10 Jun 2021 08:21:46

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 30 Apr 2021 14:41:04 |
| User signature succeeded. | Milton Haber (b) (4) | 29 Apr 2021 15:47:47 |
| Reviewed for Safety. | (b) (4) (u) (4), (b) (6) | 29 Apr 2021 13:05:54 |
| User entered 'Haber' | System | 29 Apr 2021 13:05:12 |

US3572330

Folder: SAE USA-US091-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 10 Jun 2021 08:21:46

[Site Address: Street](#)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 30 Apr 2021 14:41:04 |
| User signature succeeded. | Milton Haber (b) (4) | 29 Apr 2021 15:47:47 |
| Reviewed for Safety. | (b) (4) (u) (4), (b) (6) | 29 Apr 2021 13:05:54 |
| User entered '2344 Laguna Del Mar, Suite 201' | System | 29 Apr 2021 13:05:12 |

US3572330

Folder: SAE USA-US091-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 10 Jun 2021 08:21:46

[Site Address: City](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 30 Apr 2021 14:41:04 |
| User signature succeeded. | Milton Haber (b) (4) | 29 Apr 2021 15:47:47 |
| Reviewed for Safety. | (b) (4) (u) (4), (b) (6) | 29 Apr 2021 13:05:54 |
| User entered 'Laredo' | System | 29 Apr 2021 13:05:12 |

US3572330

Folder: SAE USA-US091-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 10 Jun 2021 08:21:46

[Site Address: State](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 30 Apr 2021 14:41:04 |
| User signature succeeded. | Milton Haber (b) (4) | 29 Apr 2021 15:47:47 |
| Reviewed for Safety. | (b) (4) (u) (4), (b) (6) | 29 Apr 2021 13:05:54 |
| User entered 'TX' | System | 29 Apr 2021 13:05:12 |

US3572330

Folder: SAE USA-US091-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 10 Jun 2021 08:21:46

[Site Address: Postal Code](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 30 Apr 2021 14:41:04 |
| User signature succeeded. | Milton Haber (b) (4) | 29 Apr 2021 15:47:47 |
| Reviewed for Safety. | (b) (4) (u) (4), (b) (6) | 29 Apr 2021 13:05:54 |
| User entered '78041' | System | 29 Apr 2021 13:05:12 |

US3572330

Folder: SAE USA-US091-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 10 Jun 2021 08:21:46

[Investigator Country](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 30 Apr 2021 14:41:04 |
| User signature succeeded. | Milton Haber (b) (4) | 29 Apr 2021 15:47:47 |
| User entered 'US' | (b) (4) System | 29 Apr 2021 13:06:50 |

US3572330

Folder: SAE USA-US091-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 10 Jun 2021 08:21:46

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 29 Apr 2021 13:06:50 |

US3572330

Folder: SAE USA-US091-2021-MRNA-1273-P301000021

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 08:21:46

[Date of submission \(Pre-filled from custom function\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 30 Apr 2021 14:41:04 |
| User signature succeeded. | Milton Haber (b) (4) | 29 Apr 2021 15:47:47 |
| User entered '29/Apr/2021 06:06' | (b) (4) System | 29 Apr 2021 13:06:50 |

US3572330

Folder: SAE USA-US091-2021-MRNA-1273-P301000021

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 08:21:46

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 30 Apr 2021 14:41:04 |
| User signature succeeded. | Milton Haber (b) (4) | 29 Apr 2021 15:47:47 |
| User entered 'I' | (b) (4) (b) (4), (b) (6) | 29 Apr 2021 13:06:50 |