

US3552035 (Prod: Saint Louis University)

Generated By: KC Joubran

Generated On: 11 Aug 2021 22:49:48

All time stamps listed in this document are displayed in GMT

US3552035

Form: Participant Creation

Data signed: (b) (4) 21 Feb 2021 17:31:32

Generated On: 11 Aug 2021 22:49:48

Participant ID

US3552035

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

US3552035

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 21 Feb 2021 17:31:36

Generated On: 11 Aug 2021 22:49:48

| | |
|---|---|
| Was this visit performed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Visit date (dd MMM yyyy) | 14 AUG 2020 |
| Was visit performed at the participant's home or at the clinic? | Home <input type="radio"/> |
| | Clinic <input checked="" type="radio"/> |
| Folder OID | SCRN |

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 21 Feb 2021 17:31:36

Generated On: 11 Aug 2021 22:49:48

| | |
|---|--|
| Date of Birth (MMM yyyy) | (b) (6) 1965 |
| Age | 55 |
| Age Units | YEARS |
| Age (Derived) | 55 |
| Sex | Female <input type="radio"/> Male <input checked="" type="radio"/> |
| Ethnicity | Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/> |
| Race (Check All That Apply) | |
| White | True |
| Black | False |
| Asian | False |
| American Indian or Alaska Native | False |
| Native Hawaiian or other Pacific Islander | False |
| Other | False |
| If race is Other, specify _____ | |
| Unknown | False |
| Not reported | False |

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 21 Feb 2021 17:31:36

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| | |
|---|--|
| Date of Informed Consent (<i>dd MMM yyyy</i>) | 14 AUG 2020 |
| Month and Year of Informed Consent (derived) | AUG 2020 |
| Year of Informed Consent (derived) | 2020 |
| Protocol Version | Amendment 1 <input type="radio"/> |
| | Amendment 2 <input checked="" type="radio"/> |
| | Amendment 3 <input type="radio"/> |
| | Amendment 4 <input type="radio"/> |
| | Amendment 5 <input type="radio"/> |
| Was participant enrolled in the study? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| If No, indicate reason for screen fail | Withdrew Consent <input type="radio"/> |
| | Inclusion/Exclusion <input type="radio"/> |
| | Cohort Full <input type="radio"/> |
| | Other <input type="radio"/> |
| If reason for screen fail is Other, specify | |
| Was this participant screened previously? | Yes <input type="radio"/> |
| | No <input checked="" type="radio"/> |
| If Yes, previous participant number | |
| Enrollment Trigger | 1 |

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 21 Feb 2021 17:31:36

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 21 Feb 2021 17:31:36

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Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 21 Feb 2021 17:31:36

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| | |
|---|--|
| Condition | ANXIETY |
| Start date (dd MMM yyyy) | UN UNK 2004 |
| 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 2004 |
| Start Year (derived) | 2004 |
| Stop Month and Year (derived) | _____ |
| Stop Year (derived) | _____ |

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 21 Feb 2021 17:31:36

Generated On: 11 Aug 2021 22:49:48

| | |
|---|--|
| Condition | DEPRESSION |
| Start date (dd MMM yyyy) | UN UNK 1998 |
| Start date completely unknown | False |
| Condition ongoing at study entry | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| If No, please specify the stop date (dd MMM yyyy) | UN UNK 1999 |
| Stop date completely unknown | False |
| Start Month and Year (derived) | JAN 1998 |
| Start Year (derived) | 1998 |
| Stop Month and Year (derived) | JAN 1999 |
| Stop Year (derived) | 1999 |

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 21 Feb 2021 17:31:36

Generated On: 11 Aug 2021 22:49:48

| | |
|---|--|
| Condition | ATTENTION DEFICIT DISORDER |
| Start date (dd MMM yyyy) | UN UNK 2005 |
| 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 2005 |
| Start Year (derived) | 2005 |
| Stop Month and Year (derived) | _____ |
| Stop Year (derived) | _____ |

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 21 Feb 2021 17:31:36

Generated On: 11 Aug 2021 22:49:48

| | |
|---|--|
| Condition | REFLUX DISEASE |
| Start date (dd MMM yyyy) | UN UNK 2010 |
| Start date completely unknown | False |
| Condition ongoing at study entry | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| If No, please specify the stop date (dd MMM yyyy) _____ | |
| Stop date completely unknown | False |
| Start Month and Year (derived) | JAN 2010 |
| Start Year (derived) | 2010 |
| Stop Month and Year (derived) | _____ |
| Stop Year (derived) | _____ |

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 21 Feb 2021 17:31:36

Generated On: 11 Aug 2021 22:49:48

| | |
|---|--|
| Condition | BARRETTS ESOPHAGUST |
| Start date (dd MMM yyyy) | UN UNK 2010 |
| Start date completely unknown | False |
| Condition ongoing at study entry | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| If No, please specify the stop date (dd MMM yyyy) _____ | |
| Stop date completely unknown | False |
| Start Month and Year (derived) | JAN 2010 |
| Start Year (derived) | 2010 |
| Stop Month and Year (derived) | _____ |
| Stop Year (derived) | _____ |

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 21 Feb 2021 17:31:36

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| | |
|---|--|
| Condition | SEASONAL ALLERGIES |
| Start date (dd MMM yyyy) | UN UNK 2006 |
| 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 2006 |
| Start Year (derived) | 2006 |
| Stop Month and Year (derived) | _____ |
| Stop Year (derived) | _____ |

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 21 Feb 2021 17:31:36

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| | |
|---|--|
| Condition | INSOMNIA |
| Start date (dd MMM yyyy) | UN UNK 2010 |
| Start date completely unknown | False |
| Condition ongoing at study entry | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| If No, please specify the stop date (dd MMM yyyy) _____ | |
| Stop date completely unknown | False |
| Start Month and Year (derived) | JAN 2010 |
| Start Year (derived) | 2010 |
| Stop Month and Year (derived) | _____ |
| Stop Year (derived) | _____ |

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 21 Feb 2021 17:31:36

Generated On: 11 Aug 2021 22:49:48

| | |
|---|--|
| Condition | SHINGLES |
| Start date (dd MMM yyyy) | UN OCT 2017 |
| Start date completely unknown | False |
| Condition ongoing at study entry | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| If No, please specify the stop date (dd MMM yyyy) | UN NOV 2017 |
| Stop date completely unknown | False |
| Start Month and Year (derived) | OCT 2017 |
| Start Year (derived) | 2017 |
| Stop Month and Year (derived) | NOV 2017 |
| Stop Year (derived) | 2017 |

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 21 Feb 2021 17:31:36

Generated On: 11 Aug 2021 22:49:48

| | |
|---|--|
| Condition | BACK PAIN |
| Start date (dd MMM yyyy) | UN OCT 2017 |
| 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) | OCT 2017 |
| Start Year (derived) | 2017 |
| Stop Month and Year (derived) | _____ |
| Stop Year (derived) | _____ |

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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 21 Feb 2021 17:31:36

Generated On: 11 Aug 2021 22:49:48

| | |
|---|--|
| Condition | L4-L5 DEGENERATIVE DISK |
| Start date (dd MMM yyyy) | UN UNK 2001 |
| 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 2001 |
| Start Year (derived) | 2001 |
| Stop Month and Year (derived) | _____ |
| Stop Year (derived) | _____ |

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 21 Feb 2021 17:31:36

Generated On: 11 Aug 2021 22:49:48

| | |
|-------------------------------------|--------------------------------------|
| Were vital signs assessed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Date of assessment (dd MMM yyyy) | 14 AUG 2020 |
| Time of assessment (00:00-23:59) | 10:54 (24 HR) |
| Vital Signs Date and Time (derived) | 14 AUG 2020 10:54 |
| Height (xxx.x) | 73 in |
| Weight (xxx.x) | 216 lb |
| BMI (xxx.x) | 28.55735 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) | |

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 21 Feb 2021 17:31:36

Generated On: 11 Aug 2021 22:49:48

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

14 AUG 2020

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 21 Feb 2021 17:31:36

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Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 21 Feb 2021 17:31:36

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 21 Feb 2021 17:32:02

Generated On: 11 Aug 2021 22:49:48

| | |
|---|---|
| Was this visit performed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Visit date (dd MMM yyyy) | 14 AUG 2020 |
| Was visit performed at the participant's home or at the clinic? | Home <input type="radio"/> |
| | Clinic <input checked="" type="radio"/> |
| Folder OID | VISIT1 |

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 21 Feb 2021 17:32:01

Generated On: 11 Aug 2021 22:49:48

What was the date of randomization? (dd MMM yyyy) 14 AUG 2020

What was the participant's randomization number? 104082

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 21 Feb 2021 17:32:02

Generated On: 11 Aug 2021 22:49:48

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

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 21 Feb 2021 17:32:02

Generated On: 11 Aug 2021 22:49:48

| | |
|-------------------------------------|--|
| 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) | 14 AUG 2020 |
| Time of assessment (00:00-23:59) | 10:54 (24 HR) |
| Vital Signs Date and Time (derived) | 14 AUG 2020 10:54 |
| Temperature (xxx.x) | 97.8 F |
| Route of measurement | Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/> |
| If Other, specify | |
| Pulse (xxx) | 68 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 18 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 127 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 80 mmHg |
| Diastolic Blood Pressure units | MMHG |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 21 Feb 2021 17:32:02

Generated On: 11 Aug 2021 22:49:48

| | |
|-------------------------------------|--|
| 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) | 14 AUG 2020 |
| Time of assessment (00:00-23:59) | 12:53 (24 HR) |
| Vital Signs Date and Time (derived) | 14 AUG 2020 12:53 |
| Temperature (xxx.x) | 97.7 F |
| Route of measurement | Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/> |
| If Other, specify | |
| Pulse (xxx) | 60 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 20 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 128 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 77 mmHg |
| Diastolic Blood Pressure units | MMHG |

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 21 Feb 2021 17:31:36

Generated On: 11 Aug 2021 22:49:48

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 21 Feb 2021 17:31:36

Generated On: 11 Aug 2021 22:49:48

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) 14 AUG 2020

What was the treatment time? (00:00-23:59) 12:23 (24 HR)

Treatment Date and Time (derived) 14 AUG 2020 12:23

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 21 Feb 2021 17:31:36

Generated On: 11 Aug 2021 22:49:48

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

14 AUG 2020

Collection time (00:00-23:59)

11:28 (24 HR)

Collection date and time (derived)

14 AUG 2020 11:28

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 21 Feb 2021 17:31:36

Generated On: 11 Aug 2021 22:49:48

| | | | |
|-------------------------------|---------------------------|---------------------------------|------------------------------------|
| Collection date (dd MMM yyyy) | | | 14 AUG 2020 |
| Lab Test | Was the sample collected? | Collection time (00:00 - 23:59) | Collection date and time (derived) |
| Nasopharyngeal Swab 1 | Yes | 11:33 | 14 AUG 2020 11:33 |
| Nasopharyngeal Swab 2 | No | | |

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 17:31:36

Generated On: 11 Aug 2021 22:49:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:49:48

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

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 AUG 2020 13:03

PC Open Date & Time

14 AUG 2020 12:43

PC Close Date & Time

14 AUG 2020 15:13

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:49:48

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒
No ☐

Please record your **TEMPERATURE** in °F

96.8 °F

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

Yes ☐
No ☒

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

| | |
|----------------------|-------------------|
| PC Time Stamp | 15 AUG 2020 10:44 |
| PC Open Date & Time | 14 AUG 2020 16:08 |
| PC Close Date & Time | 15 AUG 2020 11:59 |

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:49:48

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 AUG 2020 00:23

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3552035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:49:48

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 AUG 2020 22:43

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3552035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:49:48

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

96.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

18 AUG 2020 02:12

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3552035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:49:48

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

97.6 °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

19 AUG 2020 00:55

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3552035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:49:48

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

20 AUG 2020 02:35

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3552035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:49:48

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

20 AUG 2020 23:38

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3552035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:49:48

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☒

No ☐

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

14 AUG 2020 13:05

PC Open Date & Time

14 AUG 2020 12:43

PC Close Date & Time

14 AUG 2020 15:13

US3552035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:49:48

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

15 AUG 2020 10:54

PC Open Date & Time

14 AUG 2020 16:08

PC Close Date & Time

15 AUG 2020 11:59

US3552035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:49:48

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

16 AUG 2020 00:25

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3552035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:49:48

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

16 AUG 2020 22:43

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3552035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:49:48

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

18 AUG 2020 02:13

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3552035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:49:48

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

19 AUG 2020 00:56

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3552035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:49:48

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

20 AUG 2020 02:35

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3552035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:49:48

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

20 AUG 2020 23:38

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:49:48

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 ☐

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:49:48

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

No ☒

Yes ☐

| | |
|----------------------|-------------------|
| PC Time stamp | 14 AUG 2020 13:06 |
| PC Open Date & Time | 14 AUG 2020 12:43 |
| PC Close Date & Time | 14 AUG 2020 15:13 |

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:49:48

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 ☐

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:49:48

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

No ☒

Yes ☐

| | |
|----------------------|-------------------|
| PC Time stamp | 15 AUG 2020 10:55 |
| PC Open Date & Time | 14 AUG 2020 16:08 |
| PC Close Date & Time | 15 AUG 2020 11:59 |

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:49:48

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 ☒

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:49:48

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 16 AUG 2020 00:26 |
| PC Open Date & Time | 15 AUG 2020 12:00 |
| PC Close Date & Time | 16 AUG 2020 11:59 |

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:49:48

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

EAB) (1725)

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US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:49:48

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 16 AUG 2020 22:43 |
| PC Open Date & Time | 16 AUG 2020 12:00 |
| PC Close Date & Time | 17 AUG 2020 11:59 |

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:49:48

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:49:48

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 18 AUG 2020 02:13 |
| PC Open Date & Time | 17 AUG 2020 12:00 |
| PC Close Date & Time | 18 AUG 2020 11:59 |

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:49:48

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:49:48

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 19 AUG 2020 00:56 |
| PC Open Date & Time | 18 AUG 2020 12:00 |
| PC Close Date & Time | 19 AUG 2020 11:59 |

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:49:48

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:49:48

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 20 AUG 2020 02:35 |
| PC Open Date & Time | 19 AUG 2020 12:00 |
| PC Close Date & Time | 20 AUG 2020 11:59 |

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:49:48

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

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Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:49:48

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 20 AUG 2020 23:39 |
| PC Open Date & Time | 20 AUG 2020 12:00 |
| PC Close Date & Time | 21 AUG 2020 11:59 |

US3552035

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 17:31:36

Generated On: 11 Aug 2021 22:49:48

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3552035

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 17:31:36

Generated On: 11 Aug 2021 22:49:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552035

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 17:31:35

Generated On: 11 Aug 2021 22:49:48

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3552035

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 17:31:35

Generated On: 11 Aug 2021 22:49:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552035

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 17:31:35

Generated On: 11 Aug 2021 22:49:48

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

04 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3552035

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 17:31:35

Generated On: 11 Aug 2021 22:49:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552035

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 21 Feb 2021 17:32:02

Generated On: 11 Aug 2021 22:49:48

| | |
|---|---|
| Was this visit performed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Visit date (dd MMM yyyy) | 17 SEP 2020 |
| Was visit performed at the participant's home or at the clinic? | Home <input type="radio"/> |
| | Clinic <input checked="" type="radio"/> |
| Folder OID | VISIT2 |

US3552035

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 21 Feb 2021 17:32:03

Generated On: 11 Aug 2021 22:49:48

| | |
|-------------------------------------|---|
| 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) | 17 SEP 2020 |
| Time of assessment (00:00-23:59) | 12:45 (24 HR) |
| Vital Signs Date and Time (derived) | 17 SEP 2020 12:45 |
| Temperature (xxx.x) | 97.7 F |
| Route of measurement | Oral <input checked="" type="radio"/> |
| | Axillary <input type="radio"/> |
| | Other <input type="radio"/> |
| If Other, specify | |
| Pulse (xxx) | 66 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 16 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 120 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 74 mmHg |
| Diastolic Blood Pressure units | MMHG |

US3552035

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 21 Feb 2021 17:32:03

Generated On: 11 Aug 2021 22:49:48

| | |
|-------------------------------------|---|
| Timepoint | Pre-Dose <input type="checkbox"/> |
| | Post-Dose <input checked="" type="checkbox"/> |
| Were vital signs assessed? | Yes <input type="checkbox"/> |
| | No <input checked="" type="checkbox"/> |
| Date of assessment (dd MMM yyyy) | |
| Time of assessment (00:00-23:59) | |
| Vital Signs Date and Time (derived) | |
| Temperature (xxx.x) | |
| Route of measurement | Oral <input type="checkbox"/> |
| | Axillary <input type="checkbox"/> |
| | Other <input type="checkbox"/> |
| 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 | |

US3552035

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 21 Feb 2021 17:32:02

Generated On: 11 Aug 2021 22:49:48

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

17 SEP 2020

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

US3552035

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 21 Feb 2021 17:32:02

Generated On: 11 Aug 2021 22:49:48

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 SHINGLES INFECTION

What was the study treatment? _____

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

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

Treatment Date and Time (derived) _____

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

What was the frequency of the study treatment dosing? _____

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

US3552035

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 21 Feb 2021 17:32:02

Generated On: 11 Aug 2021 22:49:48

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

17 SEP 2020

Collection time (00:00-23:59)

13:11 (24 HR)

Collection date and time (derived)

17 SEP 2020 13:11

US3552035

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 21 Feb 2021 17:32:02

Generated On: 11 Aug 2021 22:49:48

| | | | |
|-------------------------------|---------------------------|---------------------------------|------------------------------------|
| Collection date (dd MMM yyyy) | | | 17 SEP 2020 |
| Lab Test | Was the sample collected? | Collection time (00:00 - 23:59) | Collection date and time (derived) |
| Nasopharyngeal Swab 1 | Yes | 13:14 | 17 SEP 2020 13:14 |
| Nasopharyngeal Swab 2 | No | | |

US3552035

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 17:32:02

Generated On: 11 Aug 2021 22:49:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552035

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 17:31:35

Generated On: 11 Aug 2021 22:49:48

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

24 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3552035

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 17:31:35

Generated On: 11 Aug 2021 22:49:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552035

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 17:31:35

Generated On: 11 Aug 2021 22:49:48

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

01 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3552035

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 17:31:35

Generated On: 11 Aug 2021 22:49:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552035

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 17:31:36

Generated On: 11 Aug 2021 22:49:48

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

08 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3552035

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 17:31:35

Generated On: 11 Aug 2021 22:49:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552035

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 21 Feb 2021 17:32:03

Generated On: 11 Aug 2021 22:49:48

| | |
|---|---|
| Was this visit performed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Visit date (dd MMM yyyy) | 12 OCT 2020 |
| Was visit performed at the participant's home or at the clinic? | Home <input type="radio"/> |
| | Clinic <input checked="" type="radio"/> |
| Folder OID | VISIT3 |

US3552035

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 21 Feb 2021 17:32:03

Generated On: 11 Aug 2021 22:49:48

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) _____

US3552035

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 21 Feb 2021 17:32:03

Generated On: 11 Aug 2021 22:49:48

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.

US3552035

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 21 Feb 2021 17:32:03

Generated On: 11 Aug 2021 22:49:48

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

12 OCT 2020

Collection time (00:00-23:59)

11:00 (24 HR)

Collection date and time (derived)

12 OCT 2020 11:00

US3552035

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 17:32:03

Generated On: 11 Aug 2021 22:49:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552035

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

TIMEPOINT

DAY 64

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

No ☒

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

14 OCT 2020 00:50:40

Patient Cloud Open Date & Time

14 OCT 2020 00:01

Patient Cloud Close Date & Time

18 OCT 2020 23:59

US3552035

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

TIMEPOINT

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 OCT 2020 14:50:50

Patient Cloud Open Date & Time

21 OCT 2020 00:01

Patient Cloud Close Date & Time

25 OCT 2020 23:59

US3552035

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

TIMEPOINT

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 OCT 2020 13:24:00

Patient Cloud Open Date & Time

28 OCT 2020 00:01

Patient Cloud Close Date & Time

01 NOV 2020 23:59

US3552035

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

| TIMEPOINT | DAY 92 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input 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 | 11 NOV 2020 23:49:08 |
| Patient Cloud Open Date & Time | 11 NOV 2020 00:01 |
| Patient Cloud Close Date & Time | 15 NOV 2020 23:59 |

US3552035

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

TIMEPOINT

DAY 99

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 NOV 2020 00:01:24

Patient Cloud Open Date & Time

18 NOV 2020 00:01

Patient Cloud Close Date & Time

22 NOV 2020 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

TIMEPOINT

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

23 NOV 2020 02:02:36

Patient Cloud Open Date & Time

22 NOV 2020 00:01

Patient Cloud Close Date & Time

26 NOV 2020 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

| 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 | 29 NOV 2020 00:02:45 |
| Patient Cloud Open Date & Time | 29 NOV 2020 00:01 |
| Patient Cloud Close Date & Time | 03 DEC 2020 23:59 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

TIMEPOINT

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

10 DEC 2020 11:28:33

Patient Cloud Open Date & Time

06 DEC 2020 00:01

Patient Cloud Close Date & Time

10 DEC 2020 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

| | |
|---|--|
| TIMEPOINT | DAY 124 |
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Date and time of submission | 13 DEC 2020 18:10:58 |
| Patient Cloud Open Date & Time | 13 DEC 2020 00:01 |
| Patient Cloud Close Date & Time | 17 DEC 2020 23:59 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

TIMEPOINT

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 DEC 2020 00:01:18

Patient Cloud Open Date & Time

20 DEC 2020 00:01

Patient Cloud Close Date & Time

24 DEC 2020 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

TIMEPOINT

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 DEC 2020 02:13:52

Patient Cloud Open Date & Time

27 DEC 2020 00:01

Patient Cloud Close Date & Time

31 DEC 2020 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

| | |
|---|--|
| TIMEPOINT | DAY 145 |
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Date and time of submission | 03 JAN 2021 00:01:33 |
| Patient Cloud Open Date & Time | 03 JAN 2021 00:01 |
| Patient Cloud Close Date & Time | 07 JAN 2021 23:59 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

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

10 JAN 2021 11:08:12

Patient Cloud Open Date & Time

10 JAN 2021 00:01

Patient Cloud Close Date & Time

14 JAN 2021 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

| | |
|---|--|
| TIMEPOINT | DAY 159 |
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Date and time of submission | 17 JAN 2021 00:20:15 |
| Patient Cloud Open Date & Time | 17 JAN 2021 00:01 |
| Patient Cloud Close Date & Time | 21 JAN 2021 23:59 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

| | |
|---|--|
| TIMEPOINT | DAY 166 |
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Date and time of submission | 24 JAN 2021 00:04:57 |
| Patient Cloud Open Date & Time | 24 JAN 2021 00:01 |
| Patient Cloud Close Date & Time | 28 JAN 2021 23:59 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

TIMEPOINT

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 FEB 2021 11:43:40

Patient Cloud Open Date & Time

31 JAN 2021 00:01

Patient Cloud Close Date & Time

04 FEB 2021 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

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 ☒

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 FEB 2021 00:41:15

Patient Cloud Open Date & Time

07 FEB 2021 00:01

Patient Cloud Close Date & Time

11 FEB 2021 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

| TIMEPOINT | DAY 187 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Date and time of submission | 17 FEB 2021 13:33:04 |
| Patient Cloud Open Date & Time | 14 FEB 2021 00:01 |
| Patient Cloud Close Date & Time | 18 FEB 2021 23:59 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

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

25 FEB 2021 20:39:34

Patient Cloud Open Date & Time

21 FEB 2021 00:01

Patient Cloud Close Date & Time

25 FEB 2021 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

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

02 MAR 2021 00:04:38

Patient Cloud Open Date & Time

28 FEB 2021 00:01

Patient Cloud Close Date & Time

04 MAR 2021 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

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

07 MAR 2021 09:30:27

Patient Cloud Open Date & Time

07 MAR 2021 00:01

Patient Cloud Close Date & Time

11 MAR 2021 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

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

14 MAR 2021 00:03:10

Patient Cloud Open Date & Time

14 MAR 2021 00:01

Patient Cloud Close Date & Time

18 MAR 2021 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

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

21 MAR 2021 11:42:37

Patient Cloud Open Date & Time

21 MAR 2021 00:01

Patient Cloud Close Date & Time

25 MAR 2021 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

TIMEPOINT

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 MAR 2021 00:05:27

Patient Cloud Open Date & Time

28 MAR 2021 00:01

Patient Cloud Close Date & Time

01 APR 2021 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

| | |
|---|--|
| TIMEPOINT | DAY 236 |
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Date and time of submission | 06 APR 2021 12:00:25 |
| Patient Cloud Open Date & Time | 04 APR 2021 00:01 |
| Patient Cloud Close Date & Time | 08 APR 2021 23:59 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

TIMEPOINT

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

12 APR 2021 10:52:13

Patient Cloud Open Date & Time

11 APR 2021 00:01

Patient Cloud Close Date & Time

15 APR 2021 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

| | |
|---|--|
| TIMEPOINT | DAY 250 |
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Date and time of submission | 18 APR 2021 00:02:27 |
| Patient Cloud Open Date & Time | 18 APR 2021 00:01 |
| Patient Cloud Close Date & Time | 22 APR 2021 23:59 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

TIMEPOINT

DAY 257

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 APR 2021 00:04:50

Patient Cloud Open Date & Time

25 APR 2021 00:01

Patient Cloud Close Date & Time

29 APR 2021 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

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 ☒

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 00:03:25

Patient Cloud Open Date & Time

02 MAY 2021 00:01

Patient Cloud Close Date & Time

06 MAY 2021 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

| 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"/> |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

13 MAY 2021 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

TIMEPOINT

DAY 278

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

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

[Patient Cloud Close Date & Time](#)

20 MAY 2021 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

| 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"/> |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

27 MAY 2021 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

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

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

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

[Patient Cloud Close Date & Time](#)

03 JUN 2021 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

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

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

10 JUN 2021 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

| 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"/> |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 JUN 2021 00:01

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17 JUN 2021 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

TIMEPOINT

DAY 313

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

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

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24 JUN 2021 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

| 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"/> |

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

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

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01 JUL 2021 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

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

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUL 2021 00:01

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08 JUL 2021 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

| 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"/> |

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

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

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

Date and time of submission

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11 JUL 2021 00:01

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15 JUL 2021 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

| 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"/> |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

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

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22 JUL 2021 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

| 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"/> |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

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

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29 JUL 2021 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

| TIMEPOINT | DAY 355 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

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

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05 AUG 2021 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

| TIMEPOINT | DAY 362 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 AUG 2021 00:01

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12 AUG 2021 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

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 ☐

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

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

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19 AUG 2021 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

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 ☐

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

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

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26 AUG 2021 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

| TIMEPOINT | DAY 383 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

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

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02 SEP 2021 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

| 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"/> |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

09 SEP 2021 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

| 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 <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"/> |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

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

[Patient Cloud Close Date & Time](#)

16 SEP 2021 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

| 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"/> |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

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

[Patient Cloud Close Date & Time](#)

23 SEP 2021 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

| 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"/> |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

30 SEP 2021 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

| 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"/> |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

07 OCT 2021 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

| 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"/> |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

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

[Patient Cloud Close Date & Time](#)

14 OCT 2021 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

| TIMEPOINT | DAY 432 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> 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"/> |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

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

[Patient Cloud Close Date & Time](#)

21 OCT 2021 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

| 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"/> |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

28 OCT 2021 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

| 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"/> |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

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

[Patient Cloud Close Date & Time](#)

04 NOV 2021 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

| 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"/> |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

11 NOV 2021 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

| 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"/> |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

18 NOV 2021 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

TIMEPOINT

DAY 467

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

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

[Patient Cloud Close Date & Time](#)

25 NOV 2021 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

| TIMEPOINT | DAY 474 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

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

[Patient Cloud Close Date & Time](#)

02 DEC 2021 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

| 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"/> |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

09 DEC 2021 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

| 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"/> |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

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

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

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

| TIMEPOINT | DAY 495 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

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

[Patient Cloud Close Date & Time](#)

23 DEC 2021 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

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 ☐

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

30 DEC 2021 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

TIMEPOINT

DAY 509

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JAN 2022 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

| 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"/> |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

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

[Patient Cloud Close Date & Time](#)

13 JAN 2022 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

TIMEPOINT

DAY 523

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

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

[Patient Cloud Close Date & Time](#)

20 JAN 2022 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

| TIMEPOINT | DAY 530 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

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

[Patient Cloud Close Date & Time](#)

27 JAN 2022 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

TIMEPOINT

DAY 537

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

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

[Patient Cloud Close Date & Time](#)

03 FEB 2022 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

| 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"/> |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

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

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10 FEB 2022 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

| TIMEPOINT | DAY 551 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

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

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

Date and time of submission

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13 FEB 2022 00:01

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17 FEB 2022 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

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 ☐

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

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

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

Date and time of submission

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20 FEB 2022 00:01

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24 FEB 2022 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

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 ☐

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

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

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

Date and time of submission

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03 MAR 2022 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

TIMEPOINT

DAY 572

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

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

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

Date and time of submission

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06 MAR 2022 00:01

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10 MAR 2022 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

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 ☐

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

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

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

Date and time of submission

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13 MAR 2022 00:01

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17 MAR 2022 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

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 ☐

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

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

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

Date and time of submission

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20 MAR 2022 00:01

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24 MAR 2022 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

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 ☐

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

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

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

Date and time of submission

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31 MAR 2022 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

| 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"/> |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

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

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

Date and time of submission

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07 APR 2022 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

| 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"/> |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

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

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

Date and time of submission

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14 APR 2022 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

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 ☐ 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 ☐

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

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

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

Date and time of submission

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US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

| 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"/> |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

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

Date and time of submission

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

| TIMEPOINT | DAY 628 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

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

[Patient Cloud Close Date & Time](#)

05 MAY 2022 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

TIMEPOINT

DAY 635

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2022 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

| TIMEPOINT | DAY 642 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

19 MAY 2022 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

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 ☐

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

26 MAY 2022 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

TIMEPOINT

DAY 656

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2022 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

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 ☐

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

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

[Patient Cloud Close Date & Time](#)

09 JUN 2022 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

TIMEPOINT

DAY 670

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

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

[Patient Cloud Close Date & Time](#)

16 JUN 2022 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

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 ☐

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

23 JUN 2022 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

TIMEPOINT

DAY 684

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 JUN 2022 00:01

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30 JUN 2022 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

| 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"/> |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

07 JUL 2022 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

| TIMEPOINT | DAY 698 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

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

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

Date and time of submission

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10 JUL 2022 00:01

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14 JUL 2022 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

| TIMEPOINT | DAY 705 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

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

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

Date and time of submission

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17 JUL 2022 00:01

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21 JUL 2022 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

| 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"/> |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUL 2022 00:01

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28 JUL 2022 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

| 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"/> |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

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

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04 AUG 2022 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

| 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"/> |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

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

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

Date and time of submission

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11 AUG 2022 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

| TIMEPOINT | DAY 733 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

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

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

Date and time of submission

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18 AUG 2022 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

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

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

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

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

Date and time of submission

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25 AUG 2022 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

| 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"/> |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

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

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

Date and time of submission

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28 AUG 2022 00:01

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01 SEP 2022 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

| 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"/> |

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

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

Date and time of submission

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08 SEP 2022 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

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

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

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

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

Date and time of submission

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US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

| 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"/> |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

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

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

Date and time of submission

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22 SEP 2022 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

| TIMEPOINT | DAY 775 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |

US3552035

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Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

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

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

Date and time of submission

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29 SEP 2022 23:59

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

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 ☐

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

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

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06 OCT 2022 23:59

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

| TIMEPOINT | DAY 789 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

13 OCT 2022 23:59

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

| 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"/> |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

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

[Patient Cloud Close Date & Time](#)

20 OCT 2022 23:59

US3552035

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 11 Aug 2021 22:49:48

| Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other? | Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache? | Date & Time of Submission |
|---|--|---------------------------|
| No | | 02 MAR 2021 00:04:50 |

US3552035

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 17:31:36

Generated On: 11 Aug 2021 22:49:48

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3552035

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 17:31:36

Generated On: 11 Aug 2021 22:49:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552035

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 17:31:35

Generated On: 11 Aug 2021 22:49:48

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

14 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3552035

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 17:31:35

Generated On: 11 Aug 2021 22:49:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552035

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 17:31:35

Generated On: 11 Aug 2021 22:49:48

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3552035

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 17:31:35

Generated On: 11 Aug 2021 22:49:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552035

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 17:31:35

Generated On: 11 Aug 2021 22:49:48

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3552035

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 17:31:35

Generated On: 11 Aug 2021 22:49:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552035

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 09 Mar 2021 16:50:14

Generated On: 11 Aug 2021 22:49:48

| | |
|---|---|
| Was this visit performed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Visit date (dd MMM yyyy) | 02 MAR 2021 |
| Was visit performed at the participant's home or at the clinic? | Home <input type="radio"/> |
| | Clinic <input checked="" type="radio"/> |
| Folder OID | VISIT4 |

US3552035

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 30 Mar 2021 16:18:22

Generated On: 11 Aug 2021 22:49:48

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) _____

US3552035

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 09 Mar 2021 16:50:13

Generated On: 11 Aug 2021 22:49:48

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.

US3552035

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 09 Mar 2021 16:50:13

Generated On: 11 Aug 2021 22:49:48

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

02 MAR 2021

Collection time (00:00-23:59)

10:33 (24 HR)

Collection date and time (derived)

02 MAR 2021 10:33

US3552035

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 09 Mar 2021 16:50:13

Generated On: 11 Aug 2021 22:49:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552035

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 16 Apr 2021 17:58:04

Generated On: 11 Aug 2021 22:49:48

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3552035

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 17:58:04

Generated On: 11 Aug 2021 22:49:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552035

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:48

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

US3552035

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:49:48

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3552035

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:49:48

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

US3552035

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 11 Aug 2021 22:49:48

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3552035

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

Form: Visit Date

Data signed: (b) (4) 21 Feb 2021 17:31:34

Generated On: 11 Aug 2021 22:49:48

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

| | |
|--------------------------|-------------|
| Visit date (dd MMM yyyy) | 19 JAN 2021 |
|--------------------------|-------------|

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

| | |
|------------|---------------|
| Folder OID | UNBLND_DECIDE |
|------------|---------------|

US3552035

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

Form: Unblinding

Data signed: (b) (4) 23 Mar 2021 15:20:10

Generated On: 11 Aug 2021 22:49:48

| | |
|---|---|
| Date of updated informed consent (<i>dd MMM yyyy</i>) | 19 JAN 2021 |
| N/A - Subject Unblinded under Amendment 5 and Discontinued from Study | False |
| Was the participant unblinded? | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Under what version of the Protocol was the Participant unblinded? | Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/> |
| Date of unblinding (<i>dd MMM yyyy</i>) | 19 JAN 2021 |
| 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 type="radio"/> Placebo <input type="radio"/> Not Administered <input checked="" type="radio"/> |
| Will participant receive mRNA-1273? | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Placebo Only Flag | |
| Continuing with mRNA-1273 | 1 |

US3552035

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 21 Feb 2021 17:31:34

Generated On: 11 Aug 2021 22:49:48

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

US3552035

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 21 Feb 2021 17:31:34

Generated On: 11 Aug 2021 22:49:48

| | |
|-------------------------------------|--|
| Height | ND - Not Done |
| Weight | ND - Not Done |
| BMI (xxx.x) | |
| Timepoint | Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/> |
| Were vital signs assessed? | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Date of assessment (dd MMM yyyy) | 19 JAN 2021 |
| Time of assessment (00:00-23:59) | 14:10 (24 HR) |
| Vital Signs Date and Time (derived) | 19 JAN 2021 14:10 |
| Temperature (xxx.x) | 98.3 F |
| Route of measurement | Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/> |
| If Other, specify | |
| Pulse (xxx) | 68 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 14 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 123 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 74 mmHg |
| Diastolic Blood Pressure units | MMHG |

US3552035

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 21 Feb 2021 17:31:34

Generated On: 11 Aug 2021 22:49:48

| | |
|-------------------------------------|--|
| Height | ND - Not Done |
| Weight | ND - Not Done |
| BMI (xxx.x) | |
| Timepoint | Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/> |
| Were vital signs assessed? | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Date of assessment (dd MMM yyyy) | 19 JAN 2021 |
| Time of assessment (00:00-23:59) | 15:14 (24 HR) |
| Vital Signs Date and Time (derived) | 19 JAN 2021 15:14 |
| Temperature (xxx.x) | 98.1 F |
| Route of measurement | Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/> |
| If Other, specify | |
| Pulse (xxx) | 69 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 14 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 132 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 86 mmHg |
| Diastolic Blood Pressure units | MMHG |

US3552035

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

Form: Physical Examination

Data signed: (b) (4) 21 Feb 2021 17:31:34

Generated On: 11 Aug 2021 22:49:48

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

19 JAN 2021

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

US3552035

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

Form: Exposure

Data signed: (b) (4) 21 Feb 2021 17:31:34

Generated On: 11 Aug 2021 22:49:48

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 19 JAN 2021

What was the treatment time? (00:00-23:59) 14:44 (24 HR)

Treatment Date and Time (derived) 19 JAN 2021 14:44

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

US3552035

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 21 Feb 2021 17:31:34

Generated On: 11 Aug 2021 22:49:48

| | |
|------------------------------------|--------------------------------------|
| Was the sample collected? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Collection date (dd MMM yyyy) | 19 JAN 2021 |
| Collection time (00:00-23:59) | 14:03 (24 HR) |
| Collection date and time (derived) | 19 JAN 2021 14:03 |

US3552035

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 21 Feb 2021 17:31:34

Generated On: 11 Aug 2021 22:49:48

| | |
|------------------------------------|--------------------------------------|
| Was the sample collected? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Collection date (dd MMM yyyy) | 19 JAN 2021 |
| Collection time (00:00 - 23:59) | 14:06 |
| Collection Date and Time (derived) | 19 JAN 2021 14:06 |

US3552035

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

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 17:31:34

Generated On: 11 Aug 2021 22:49:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3552035

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 17:31:36

Generated On: 11 Aug 2021 22:49:48

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

US3552035

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 17:31:36

Generated On: 11 Aug 2021 22:49:48

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

US3552035

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 09 Mar 2021 16:50:13

Generated On: 11 Aug 2021 22:49:48

| | |
|---|---|
| Was this visit performed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Visit date (dd MMM yyyy) | 02 MAR 2021 |
| Was visit performed at the participant's home or at the clinic? | Home <input type="radio"/> |
| | Clinic <input checked="" type="radio"/> |
| Folder OID | OLD29 |

US3552035

Folder: OL-D29 (1)

Form: Vital Signs

Data signed: (b) (4) 09 Mar 2021 16:50:13

Generated On: 11 Aug 2021 22:49:48

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) _____

US3552035

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 09 Mar 2021 16:50:13

Generated On: 11 Aug 2021 22:49:48

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.

US3552035

Folder: OL-D29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 09 Mar 2021 16:50:13

Generated On: 11 Aug 2021 22:49:48

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

02 MAR 2021

Collection time (00:00-23:59)

10:33 (24 HR)

Collection date and time (derived)

02 MAR 2021 10:33

US3552035

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 21 Feb 2021 17:31:32

Generated On: 11 Aug 2021 22:49:48

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3552035

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 21 Feb 2021 17:31:32

Generated On: 11 Aug 2021 22:49:48

| | |
|--|--|
| AEID | |
| Adverse event | SHINGLES |
| Was this a medically-attended AE? | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Was this a Solicited Adverse Reaction? | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Is this event a confirmed diagnosis of Symptomatic Covid-19? | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Start date (dd MMM yyyy) | 04 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) | 21 SEP 2020 |
| End time (00:00-23:59) | |
| AE End Date and Time (derived) | |
| Severity | Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/> |
| Is the adverse event serious? | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| AE is serious due To (check all that apply) | |
| Death | False |
| Life threatening | False |
| Requires inpatient or prolongation of existing Hospitalization | False |
| Hospital Admission Date (dd MMM yyyy) | |
| Hospital Discharge Date (dd MMM yyyy) | |
| Admitted to ICU? | Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/> |
| Number of Days in ICU | |

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US3552035

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 21 Feb 2021 17:31:32

Generated On: 11 Aug 2021 22:49:48

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

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 21 Feb 2021 17:31:34

Generated On: 11 Aug 2021 22:49:48

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

Yes ☒

No ☐

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

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 21 Feb 2021 17:31:32

Generated On: 11 Aug 2021 22:49:48

Name of Medication SERTRALINE

Prophylaxis Yes ☐
No ☒

Indication ANXIETY

Dose per administration 150

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 21 Feb 2021 17:31:32

Generated On: 11 Aug 2021 22:49:48

| | | |
|--|--------------------------|----------------------------------|
| | Intramuscular | <input type="radio"/> |
| | Respiratory (Inhalation) | <input type="radio"/> |
| | Intralesional | <input type="radio"/> |
| | Intraperitoneal | <input type="radio"/> |
| | Nasal | <input type="radio"/> |
| | Vaginal | <input type="radio"/> |
| | Rectal | <input type="radio"/> |
| | Intravenous | <input type="radio"/> |
| | Intravenous Bolus | <input type="radio"/> |
| | Intravenous Drip | <input type="radio"/> |
| | Other | <input type="radio"/> |
| If route of administration is Other, specify _____ | | |
| Start date (dd MMM yyyy) | UN UNK 2004 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input checked="" type="radio"/> |
| | No | <input type="radio"/> |
| If not Ongoing, End date (dd MMM yyyy) _____ | | |
| Was this medication taken for solicited event? | Yes | <input type="radio"/> |
| | No | <input checked="" type="radio"/> |
| Separate Dosage Number (derived) | 1 | |
| Interval Dosage Unit Number (derived) | 1 | |
| Interval Dosage Definition (derived) | 802 | <input type="radio"/> |
| | 803 | <input type="radio"/> |
| | 804 | <input checked="" type="radio"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 21 Feb 2021 17:31:32

Generated On: 11 Aug 2021 22:49:48

Name of Medication METHYLPHENIDATE

Prophylaxis Yes ☐
No ☒

Indication ATTENTION DEFICIT DISORDER

Dose per administration 54

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 21 Feb 2021 17:31:32

Generated On: 11 Aug 2021 22:49:48

| | | |
|--|--------------------------|----------------------------------|
| | Intramuscular | <input type="checkbox"/> |
| | Respiratory (Inhalation) | <input type="checkbox"/> |
| | Intralesional | <input type="checkbox"/> |
| | Intraperitoneal | <input type="checkbox"/> |
| | Nasal | <input type="checkbox"/> |
| | Vaginal | <input type="checkbox"/> |
| | Rectal | <input type="checkbox"/> |
| | Intravenous | <input type="checkbox"/> |
| | Intravenous Bolus | <input type="checkbox"/> |
| | Intravenous Drip | <input type="checkbox"/> |
| | Other | <input type="checkbox"/> |
| If route of administration is Other, specify _____ | | |
| Start date (dd MMM yyyy) | UN UNK 2005 | |
| 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"/> |

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 21 Feb 2021 17:31:32

Generated On: 11 Aug 2021 22:49:48

Name of Medication OMEPRAZOLE

Prophylaxis Yes ☐
No ☒

Indication REFLUX DISEASE

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 ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 21 Feb 2021 17:31:32

Generated On: 11 Aug 2021 22:49:48

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 21 Feb 2021 17:31:32

Generated On: 11 Aug 2021 22:49:48

Name of Medication NAPROXEN

Prophylaxis Yes ☐
No ☒

Indication BACK PAIN

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 ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 21 Feb 2021 17:31:32

Generated On: 11 Aug 2021 22:49:48

| | | |
|--|--------------------------|----------------------------------|
| | 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) | 11 AUG 2020 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input checked="" type="radio"/> |
| | No | <input type="radio"/> |
| If not Ongoing, End date (dd MMM yyyy) _____ | | |
| Was this medication taken for solicited event? | Yes | <input type="radio"/> |
| | No | <input checked="" type="radio"/> |
| Separate Dosage Number (derived) | _____ | |
| Interval Dosage Unit Number (derived) | _____ | |
| Interval Dosage Definition (derived) | 802 | <input type="radio"/> |
| | 803 | <input type="radio"/> |
| | 804 | <input type="radio"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 21 Feb 2021 17:31:32

Generated On: 11 Aug 2021 22:49:48

Name of Medication LUNESTA

Prophylaxis Yes ☐
No ☒

Indication INSOMNIA

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 21 Feb 2021 17:31:32

Generated On: 11 Aug 2021 22:49:48

| | | |
|--|--------------------------|----------------------------------|
| | Intramuscular | <input type="checkbox"/> |
| | Respiratory (Inhalation) | <input type="checkbox"/> |
| | Intralesional | <input type="checkbox"/> |
| | Intraperitoneal | <input type="checkbox"/> |
| | Nasal | <input type="checkbox"/> |
| | Vaginal | <input type="checkbox"/> |
| | Rectal | <input type="checkbox"/> |
| | Intravenous | <input type="checkbox"/> |
| | Intravenous Bolus | <input type="checkbox"/> |
| | Intravenous Drip | <input type="checkbox"/> |
| | Other | <input type="checkbox"/> |
| If route of administration is Other, specify _____ | | |
| Start date (dd MMM yyyy) | 13 AUG 2020 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input checked="" type="radio"/> |
| | No | <input type="radio"/> |
| If not Ongoing, End date (dd MMM yyyy) _____ | | |
| Was this medication taken for solicited event? | Yes | <input type="radio"/> |
| | No | <input checked="" type="radio"/> |
| Separate Dosage Number (derived) | _____ | |
| Interval Dosage Unit Number (derived) | _____ | |
| Interval Dosage Definition (derived) | 802 | <input type="radio"/> |
| | 803 | <input type="radio"/> |
| | 804 | <input type="radio"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 21 Feb 2021 17:31:32

Generated On: 11 Aug 2021 22:49:48

Name of Medication PREDNISONE

Prophylaxis Yes ☐
No ☒

Indication SHINGLES

Dose per administration 24-4

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 21 Feb 2021 17:31:32

Generated On: 11 Aug 2021 22:49:48

| | | |
|--|--------------------------|-------------------------------------|
| | 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) | | 04 SEP 2020 |
| Start date completely unknown | | False |
| Ongoing? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy) 09 SEP 2020 | | |
| Was this medication taken for solicited event? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| Separate Dosage Number (derived) | | 1 |
| Interval Dosage Unit Number (derived) | | 1 |
| Interval Dosage Definition (derived) | 802 | <input type="checkbox"/> |
| | 803 | <input type="checkbox"/> |
| | 804 | <input checked="" type="checkbox"/> |

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 21 Feb 2021 17:31:32

Generated On: 11 Aug 2021 22:49:48

Name of Medication VALACYCLOVIR

Prophylaxis Yes ☐
No ☒

Indication SHINGLES

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 21 Feb 2021 17:31:32

Generated On: 11 Aug 2021 22:49:48

| | | |
|--|--------------------------|-------------------------------------|
| | 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) | | 04 SEP 2020 |
| Start date completely unknown | | False |
| Ongoing? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy) 14 SEP 2020 | | |
| Was this medication taken for solicited event? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| Separate Dosage Number (derived) | | 3 |
| Interval Dosage Unit Number (derived) | | 1 |
| Interval Dosage Definition (derived) | 802 | <input type="checkbox"/> |
| | 803 | <input type="checkbox"/> |
| | 804 | <input checked="" type="checkbox"/> |

US3552035

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 21 Feb 2021 17:31:34

Generated On: 11 Aug 2021 22:49:48

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3552035

Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) 21 Feb 2021 17:31:34

Generated On: 11 Aug 2021 22:49:48

| | |
|--|-------------|
| Date of dosing discontinuation (dd MMM yyyy) | 17 SEP 2020 |
|--|-------------|

| | |
|---|--|
| Primary reason for dosing discontinuation | AE (specify) <input checked="" type="radio"/> |
| | SAE (specify) <input type="radio"/> |
| | Death <input type="radio"/> |
| | Lost To Follow-up <input type="radio"/> |
| | Physician decision (specify) <input type="radio"/> |
| | Pregnancy <input type="radio"/> |
| | Protocol deviation (specify) <input type="radio"/> |
| | Study Terminated By Sponsor <input type="radio"/> |
| | Withdrawal of consent by participant (specify) <input type="radio"/> |
| | Due to SARS-COV-2 <input type="radio"/> |
| | Other <input type="radio"/> |

| | |
|---|-------|
| If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify | AE #1 |
|---|-------|

US3552035

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:49:48

Date of study discontinuation/completion (*dd MMM yyyy*)

Reason for discontinuation

AE (specify) ☐

SAE (specify) ☐

Complete ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Other ☐

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

If reason for discontinuation is Death, main cause of death

Adverse event ☐

Unknown ☐

Other ☐

If main cause of death is Other, specify

Date of death (*dd MMM yyyy*)

Was autopsy performed?

Yes ☐

No ☐

Unknown ☐

Audit

US3552035 (Prod: Saint Louis University)

US3552035

Form: Participant Creation

Generated On: 11 Aug 2021 22:49:48

[Participant ID](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 29 Mar 2021 16:56:22 |
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| User entered 'US3552035' | (b) (4) RWS_ENDPOINT ENDPOINT (b) (4) | 14 Aug 2020 16:54:30 |

US3552035

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:49:48

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:36:03 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Aug 2020 17:38:33 |
| User entered 'Yes (Y)' | Mikayla Frye (b) (4) (b) (4) | 14 Aug 2020 20:03:11 |

US3552035

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:49:48

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

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:36:03 |
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 19 Aug 2020 17:38:33 |
| User entered '14 AUG 2020' | RWS_ENDPOINT ENDPOINT (b) (4) | 14 Aug 2020 16:54:31 |

US3552035

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:49:48

[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 18:36:03 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Aug 2020 17:38:33 |
| User entered 'Clinic (Clinic)' | Mikayla Frye (b) (4) (b) (4) | 14 Aug 2020 20:03:11 |

US3552035

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:49:48

[Folder OID](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:36:03 |
| User entered 'SCRN' | System | 14 Aug 2020 20:03:11 |

US3552035

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:49:48

Date of Birth (MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:36:03 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Aug 2020 17:38:50 |
| User entered (b) (6) 1965' | RWS_ENDPOINT ENDPOINT (b) (4) | 14 Aug 2020 16:54:31 |

US3552035

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:49:48

[Age](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:36:03 |
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) | 19 Aug 2020 17:38:50 |
| | (b) (4), (b) (6) | |
| User closed query 'Data is required. Please complete.' (Site from System). | System | 14 Aug 2020 20:03:42 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 14 Aug 2020 20:03:42 |
| User closed query 'Age does not fit Cohort. Please review and update.' (Site from System). | System | 14 Aug 2020 20:03:42 |
| User entered '55' reason for change: Data Entry Error | Mikayla Frye (b) (4) | 14 Aug 2020 20:03:42 |
| | (b) (4) | |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 14 Aug 2020 20:03:22 |
| User opened query 'Age does not fit Cohort. Please review and update.' (Site from System). | System | 14 Aug 2020 20:03:22 |
| User entered empty. | Mikayla Frye (b) (4) | 14 Aug 2020 20:03:22 |
| | (b) (4) | |

US3552035

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:49:48

[Age Units](#)

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:36:03 |
| User entered 'YEARS' | System | 14 Aug 2020 20:03:42 |
| User entered empty. | System | 14 Aug 2020 20:03:22 |

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Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:49:48

[Age \(Derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:36:03 |
| User entered '55' | System | 14 Aug 2020 17:04:23 |

US3552035

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:49:48

Sex

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:36:03 |
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 19 Aug 2020 17:38:50 |
| User closed query 'Data is required. Please complete.' (Site from System). | System | 14 Aug 2020 20:03:47 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 14 Aug 2020 20:03:47 |
| User entered 'Male (M)' reason for change: Data Entry Error | Mikayla Frye (b) (4) | 14 Aug 2020 20:03:47 |
| | (b) (4) | |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 14 Aug 2020 20:03:22 |
| User entered empty. | Mikayla Frye (b) (4) | 14 Aug 2020 20:03:22 |
| | (b) (4) | |

US3552035

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:49:48

[Ethnicity](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:36:03 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Aug 2020 17:38:50 |
| User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)' | Mikayla Frye (b) (4) (b) (4) | 14 Aug 2020 20:03:22 |

US3552035

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:49:48

White

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:36:03 |
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Aug 2020 17:38:50 |
| User entered 'l' | Mikayla Frye (b) (4) | 14 Aug 2020 20:03:22 |

US3552035

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:49:48

[Black](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:36:03 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Aug 2020 17:38:50 |
| User entered '0' | Mikayla Frye (b) (4) (b) (4) | 14 Aug 2020 20:03:22 |

US3552035

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:49:48

[Asian](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:36:03 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Aug 2020 17:38:50 |
| User entered '0' | Mikayla Frye (b) (4) (b) (4) | 14 Aug 2020 20:03:22 |

US3552035

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:49:48

[American Indian or Alaska Native](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:36:03 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Aug 2020 17:38:50 |
| User entered '0' | Mikayla Frye (b) (4) (b) (4) | 14 Aug 2020 20:03:22 |

US3552035

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:49:48

[Native Hawaiian or other Pacific Islander](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:36:03 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Aug 2020 17:38:50 |
| User entered '0' | Mikayla Frye (b) (4) (b) (4) | 14 Aug 2020 20:03:22 |

US3552035

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:49:48

[Other](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:36:03 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Aug 2020 17:38:50 |
| User entered '0' | Mikayla Frye (b) (4) (b) (4) | 14 Aug 2020 20:03:22 |

US3552035

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:49:48

If race is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:36:03 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Aug 2020 17:38:50 |
| User entered empty. | Mikayla Frye (b) (4) (b) (4) | 14 Aug 2020 20:03:22 |

US3552035

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:49:48

Unknown

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:36:03 |
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 19 Aug 2020 17:38:50 |
| User entered '0' | Mikayla Frye (b) (4) | 14 Aug 2020 20:03:22 |
| | (b) (4) | |

US3552035

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:49:48

[Not reported](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:36:03 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Aug 2020 17:38:50 |
| User entered '0' | Mikayla Frye (b) (4) (b) (4) | 14 Aug 2020 20:03:22 |

US3552035

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:49:48

Date of Informed Consent (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:36:03 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Aug 2020 17:39:05 |
| User entered '14 Aug 2020' | (b) (4), (b) (6) | 14 Aug 2020 17:04:23 |

US3552035

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:49:48

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:36:03 |
| User entered 'Aug 2020' | System | 14 Aug 2020 17:04:23 |

US3552035

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:49:48

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:36:03 |
| User entered '2020' | System | 14 Aug 2020 17:04:23 |

US3552035

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:49:48

[Protocol Version](#)

| Audit | User | Time (GMT) |
|--------------------------------|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:36:03 |
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) | 19 Aug 2020 17:39:05 |
| User entered 'Amendment 2 (2)' | (b) (4), (b) (6) | 14 Aug 2020 17:04:23 |

US3552035

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:49:48

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

| Audit | User | Time (GMT) |
|---------------------------|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:36:03 |
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 19 Aug 2020 17:39:05 |
| User entered 'Yes (Y)' | | 14 Aug 2020 17:04:23 |

US3552035

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:49:48

If No, indicate reason for screen fail

| Audit | User | Time (GMT) |
|---------------------------|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:36:03 |
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) | 19 Aug 2020 17:39:05 |
| User entered empty. | (b) (4), (b) (6) | 14 Aug 2020 17:04:23 |

US3552035

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:49:48

If reason for screen fail is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:36:03 |
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 19 Aug 2020 17:39:05 |
| User entered empty. | | 14 Aug 2020 17:04:23 |

US3552035

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:49:48

[Was this participant screened previously?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:36:03 |
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) | 19 Aug 2020 17:39:05 |
| User entered 'No (N)' | (b) (4), (b) (6) | 14 Aug 2020 17:04:23 |

US3552035

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:49:48

[If Yes, previous participant number](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:36:03 |
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 19 Aug 2020 17:39:05 |
| User entered empty. | RWS_ENDPOINT | 14 Aug 2020 16:54:31 |
| | ENDPOINT (b) (4) | |
| | | |

US3552035

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:49:48

[Enrollment Trigger](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:36:03 |
| User entered 'l' | System | 14 Aug 2020 17:04:33 |

US3552035

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 11 Aug 2021 22:49:48

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

| Audit | User | Time (GMT) |
|---------------------------|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:36:03 |
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 19 Aug 2020 17:39:14 |
| User entered 'Yes (Y)' | | 14 Aug 2020 17:04:33 |

US3552035

Folder: Screening

Form: Medical History Summary

Generated On: 11 Aug 2021 22:49:48

[Were any significant conditions reported?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:36:03 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Aug 2020 17:40:37 |
| User entered 'Yes (Y)' | Mikayla Frye (b) (4) (b) (4) | 14 Aug 2020 20:04:34 |

US3552035

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:49:48

[Condition](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:36:03 |
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 19 Aug 2020 17:42:20 |
| User coded data point as SOC: Psychiatric disorders, HLGT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\23.0. | Coder Import (b) (4) | 15 Aug 2020 00:10:52 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0. | Coder Import (b) (4) | 15 Aug 2020 00:10:52 |
| Data point term sent to Coder | System | 14 Aug 2020 20:05:37 |
| User entered 'Anxiety' | Mikayla Frye (b) (4) | 14 Aug 2020 20:05:03 |
| | (b) (4) | |

US3552035

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:49:48

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

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:36:03 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Aug 2020 17:42:20 |
| User entered 'UN UNK 2004' | Mikayla Frye (b) (4) (b) (4) | 14 Aug 2020 20:05:03 |

US3552035

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:49:48

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:36:03 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Aug 2020 17:42:20 |
| User entered '0' | Mikayla Frye (b) (4) (b) (4) | 14 Aug 2020 20:05:03 |

US3552035

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:49:48

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:36:03 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Aug 2020 17:42:20 |
| User entered 'Yes (Y)' | Mikayla Frye (b) (4) (b) (4) | 14 Aug 2020 20:05:03 |

US3552035

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:49:48

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

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:36:03 |
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) | 19 Aug 2020 17:42:20 |
| User entered empty. | (b) (4), (b) (6) | 19 Aug 2020 17:42:20 |
| | Mikayla Frye (b) (4) | 14 Aug 2020 20:05:03 |
| | (b) (4) | |

US3552035

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:49:48

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:36:03 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Aug 2020 17:42:20 |
| User entered '0' | Mikayla Frye (b) (4) (b) (4) | 14 Aug 2020 20:05:03 |

US3552035

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:49:48

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:36:03 |
| User entered 'Jan 2004' | System | 14 Aug 2020 20:05:03 |

US3552035

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:49:48

Start Year (derived)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:36:03 |
| User entered '2004' | System | 14 Aug 2020 20:05:03 |

US3552035

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:49:48

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:36:03 |
| User entered empty. | System | 14 Aug 2020 20:05:03 |

US3552035

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:49:48

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:36:03 |
| User entered empty. | System | 14 Aug 2020 20:05:03 |

US3552035

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:49:48

[Condition](#)

| Audit | User | Time (GMT) |
|---|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:36:03 |
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 19 Aug 2020 17:42:20 |
| User coded data point as SOC: Psychiatric disorders, HLGT: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression - version MedDRA\23.0. | Coder Import (b) (4) | 15 Aug 2020 00:11:07 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0. | Coder Import (b) (4) | 15 Aug 2020 00:11:07 |
| Data point term sent to Coder | System | 14 Aug 2020 20:06:38 |
| User entered 'Depression' | Mikayla Frye (b) (4) | 14 Aug 2020 20:05:38 |
| | (b) (4) | |

US3552035

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:49:48

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

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:36:03 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Aug 2020 17:42:20 |
| User entered 'UN UNK 1998' | Mikayla Frye (b) (4) (b) (4) | 14 Aug 2020 20:05:38 |

US3552035

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:49:48

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:36:03 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Aug 2020 17:42:20 |
| User entered '0' | Mikayla Frye (b) (4) (b) (4) | 14 Aug 2020 20:05:38 |

US3552035

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:49:48

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:36:03 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Aug 2020 17:42:20 |
| User entered 'No (N)' | Mikayla Frye (b) (4) (b) (4) | 14 Aug 2020 20:05:38 |

US3552035

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:49:48

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

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:36:03 |
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 19 Aug 2020 17:42:20 |
| User entered 'UN UNK 1999' | Mikayla Frye (b) (4) | 14 Aug 2020 20:05:38 |
| | (b) (4) | |

US3552035

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:49:48

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:36:03 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Aug 2020 17:42:20 |
| User entered '0' | Mikayla Frye (b) (4) (b) (4) | 14 Aug 2020 20:05:38 |

US3552035

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:49:48

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:36:03 |
| User entered 'Jan 1998' | System | 14 Aug 2020 20:05:38 |

US3552035

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:49:48

Start Year (derived)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:36:03 |
| User entered '1998' | System | 14 Aug 2020 20:05:38 |

US3552035

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:49:48

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:36:03 |
| User entered 'Jan 1999' | System | 14 Aug 2020 20:05:38 |

US3552035

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:49:48

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:36:03 |
| User entered '1999' | System | 14 Aug 2020 20:05:38 |

US3552035

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:49:48

[Condition](#)

| Audit | User | Time (GMT) |
|---|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:36:03 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Aug 2020 17:42:20 |
| User coded data point as SOC: Psychiatric disorders, HLGT: Cognitive and attention disorders and disturbances, HLT: Attention deficit and disruptive behaviour disorders, PT: Attention deficit hyperactivity disorder, LLT: Attention deficit disorder - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 15 Aug 2020 00:11:16 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 15 Aug 2020 00:11:16 |
| Data point term sent to Coder | System | 14 Aug 2020 20:08:46 |
| User entered 'Attention Deficit Disorder' | Mikayla Frye (b) (4) (b) (4) | 14 Aug 2020 20:08:10 |

US3552035

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:49:48

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

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:36:03 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Aug 2020 17:42:20 |
| User entered 'UN UNK 2005' | Mikayla Frye (b) (4) (b) (4) | 14 Aug 2020 20:08:10 |

US3552035

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:49:48

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:36:03 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Aug 2020 17:42:20 |
| User entered '0' | Mikayla Frye (b) (4) (b) (4) | 14 Aug 2020 20:08:10 |

US3552035

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:49:48

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:36:03 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Aug 2020 17:42:20 |
| User entered 'Yes (Y)' | Mikayla Frye (b) (4) (b) (4) | 14 Aug 2020 20:08:10 |

US3552035

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:49:48

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

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:36:03 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Aug 2020 17:42:20 |
| User entered empty. | Mikayla Frye (b) (4) (b) (4) | 14 Aug 2020 20:08:10 |

US3552035

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:49:48

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:36:03 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Aug 2020 17:42:20 |
| User entered '0' | Mikayla Frye (b) (4) (b) (4) | 14 Aug 2020 20:08:10 |

US3552035

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:49:48

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:36:03 |
| User entered 'Jan 2005' | System | 14 Aug 2020 20:08:10 |

US3552035

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:49:48

Start Year (derived)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:36:03 |
| User entered '2005' | System | 14 Aug 2020 20:08:10 |

US3552035

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:49:48

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:36:03 |
| User entered empty. | System | 14 Aug 2020 20:08:10 |

US3552035

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:49:48

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:36:03 |
| User entered empty. | System | 14 Aug 2020 20:08:10 |

US3552035

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:49:48

Condition

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:36:03 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Aug 2020 17:42:20 |
| User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastroesophageal reflux disease, LLT: Gastroesophageal reflux disease - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 15 Aug 2020 06:26:10 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 15 Aug 2020 06:26:10 |
| Data point term sent to Coder | System | 14 Aug 2020 20:08:46 |
| User entered 'Reflux disease' | Mikayla Frye (b) (4) (b) (4) | 14 Aug 2020 20:08:40 |

US3552035

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:49:48

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

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:36:03 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Aug 2020 17:42:20 |
| User entered 'UN UNK 2010' | Mikayla Frye (b) (4) (b) (4) | 14 Aug 2020 20:08:40 |

US3552035

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:49:48

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:36:03 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Aug 2020 17:42:20 |
| User entered '0' | Mikayla Frye (b) (4) (b) (4) | 14 Aug 2020 20:08:40 |

US3552035

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:49:48

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:36:03 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Aug 2020 17:42:20 |
| User entered 'Yes (Y)' | Mikayla Frye (b) (4) (b) (4) | 14 Aug 2020 20:08:40 |

US3552035

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:49:48

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

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:36:03 |
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 19 Aug 2020 17:42:20 |
| User entered empty. | Mikayla Frye (b) (4) | 14 Aug 2020 20:08:40 |
| | (b) (4) | |

US3552035

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:49:48

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:36:03 |
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) | 19 Aug 2020 17:42:20 |
| User entered '0' | (b) (4), (b) (6) | 19 Aug 2020 17:42:20 |
| | Mikayla Frye (b) (4) | 14 Aug 2020 20:08:40 |
| | (b) (4) | |

US3552035

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:49:48

Start Month and Year (derived)

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:36:03 |
| User entered 'Jan 2010' | System | 14 Aug 2020 20:08:40 |

US3552035

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:49:48

Start Year (derived)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:36:03 |
| User entered '2010' | System | 14 Aug 2020 20:08:40 |

US3552035

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:49:48

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:36:03 |
| User entered empty. | System | 14 Aug 2020 20:08:40 |

US3552035

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:49:48

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:36:03 |
| User entered empty. | System | 14 Aug 2020 20:08:40 |

US3552035

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:49:48

[Condition](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:36:03 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Aug 2020 17:42:20 |
| User coded data point as SOC: Gastrointestinal disorders, HLG: Gastrointestinal conditions NEC, HLT: Gastrointestinal mucosal dystrophies and secretion disorders, PT: Barrett's oesophagus, LLT: Barrett's oesophagus - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 15 Aug 2020 00:22:14 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 15 Aug 2020 00:22:14 |
| Data point term sent to Coder | System | 14 Aug 2020 22:38:58 |
| User entered 'BARREtS ESOPHAGUS' reason for change: Data Entry Error | Joan Siegner (b) (4) (b) (4) | 14 Aug 2020 22:38:34 |
| Data point term sent to Coder | System | 14 Aug 2020 20:09:47 |
| User entered 'Barrets Esophagus' | Mikayla Frye (b) (4) (b) (4) | 14 Aug 2020 20:09:03 |

US3552035

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:49:48

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

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:36:03 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Aug 2020 17:42:20 |
| User entered 'UN UNK 2010' | Mikayla Frye (b) (4) (b) (4) | 14 Aug 2020 20:09:03 |

US3552035

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:49:48

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:36:03 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Aug 2020 17:42:20 |
| User entered '0' | Mikayla Frye (b) (4) (b) (4) | 14 Aug 2020 20:09:03 |

US3552035

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:49:48

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:36:03 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Aug 2020 17:42:20 |
| User entered 'Yes (Y)' | Mikayla Frye (b) (4) (b) (4) | 14 Aug 2020 20:09:03 |

US3552035

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:49:48

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

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:36:03 |
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Aug 2020 17:42:20 |
| User entered empty. | Mikayla Frye (b) (4) | 14 Aug 2020 20:09:03 |

US3552035

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:49:48

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:36:03 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Aug 2020 17:42:20 |
| User entered '0' | Mikayla Frye (b) (4) (b) (4) | 14 Aug 2020 20:09:03 |

US3552035

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:49:48

Start Month and Year (derived)

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:36:03 |
| User entered 'Jan 2010' | System | 14 Aug 2020 20:09:03 |

US3552035

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:49:48

Start Year (derived)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:36:03 |
| User entered '2010' | System | 14 Aug 2020 20:09:03 |

US3552035

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:49:48

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:36:03 |
| User entered empty. | System | 14 Aug 2020 20:09:03 |

US3552035

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:49:48

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:36:03 |
| User entered empty. | System | 14 Aug 2020 20:09:03 |

US3552035

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:49:48

[Condition](#)

| Audit | User | Time (GMT) |
|---|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:36:03 |
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 19 Aug 2020 17:42:20 |
| User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\23.0. | Coder Import (b) (4) | 15 Aug 2020 00:22:13 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0. | Coder Import (b) (4) | 15 Aug 2020 00:22:13 |
| Data point term sent to Coder | System | 14 Aug 2020 22:38:58 |
| User entered 'SEASONal ALLERGIES' reason for change: Data Entry Error | Joan Siegner (b) (4) | 14 Aug 2020 22:38:49 |
| | | |
| Data point term sent to Coder | System | 14 Aug 2020 20:09:48 |
| User entered 'Season allergies' | Mikayla Frye (b) (4) | 14 Aug 2020 20:09:26 |
| | (b) (4) | |

US3552035

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:49:48

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

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:36:03 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Aug 2020 17:42:20 |
| User entered 'UN UNK 2006' | Mikayla Frye (b) (4) (b) (4) | 14 Aug 2020 20:09:26 |

US3552035

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:49:48

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:36:03 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Aug 2020 17:42:20 |
| User entered '0' | Mikayla Frye (b) (4) (b) (4) | 14 Aug 2020 20:09:26 |

US3552035

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:49:48

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:36:03 |
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 19 Aug 2020 17:42:20 |
| User entered 'Yes (Y)' | Mikayla Frye (b) (4) | 14 Aug 2020 20:09:26 |
| | (b) (4) | |

US3552035

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:49:48

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

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:36:03 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Aug 2020 17:42:20 |
| User entered empty. | Mikayla Frye (b) (4) (b) (4) | 14 Aug 2020 20:09:26 |

US3552035

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:49:48

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:36:03 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Aug 2020 17:42:20 |
| User entered '0' | Mikayla Frye (b) (4) (b) (4) | 14 Aug 2020 20:09:26 |

US3552035

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:49:48

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:36:03 |
| User entered 'Jan 2006' | System | 14 Aug 2020 20:09:26 |

US3552035

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:49:48

Start Year (derived)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:36:03 |
| User entered '2006' | System | 14 Aug 2020 20:09:26 |

US3552035

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:49:48

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:36:03 |
| User entered empty. | System | 14 Aug 2020 20:09:26 |

US3552035

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:49:48

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:36:03 |
| User entered empty. | System | 14 Aug 2020 20:09:26 |

US3552035

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:49:48

[Condition](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:36:03 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Aug 2020 17:42:20 |
| User coded data point as SOC: Psychiatric disorders, HLGT: Sleep disorders and disturbances, HLT: Disturbances in initiating and maintaining sleep, PT: Insomnia, LLT: Insomnia - version MedDRA\23.0. | Coder Import (b) (4) (b) (4) | 15 Aug 2020 00:11:23 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0. | Coder Import (b) (4) (b) (4) | 15 Aug 2020 00:11:23 |
| Data point term sent to Coder | System | 14 Aug 2020 20:09:49 |
| User entered 'Insomnia' | Mikayla Frye (b) (4) (b) (4) | 14 Aug 2020 20:09:48 |

US3552035

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:49:48

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

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:36:03 |
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Aug 2020 17:42:20 |
| User entered 'UN UNK 2010' | Mikayla Frye (b) (4) (b) (4) | 14 Aug 2020 20:09:48 |

US3552035

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:49:48

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:36:03 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Aug 2020 17:42:20 |
| User entered '0' | Mikayla Frye (b) (4) (b) (4) | 14 Aug 2020 20:09:48 |

US3552035

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:49:48

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:36:03 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Aug 2020 17:42:20 |
| User entered 'Yes (Y)' | Mikayla Frye (b) (4) (b) (4) | 14 Aug 2020 20:09:48 |

US3552035

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:49:48

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

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:36:03 |
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Aug 2020 17:42:20 |
| User entered empty. | Mikayla Frye (b) (4) | 14 Aug 2020 20:09:48 |

US3552035

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:49:48

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:36:03 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Aug 2020 17:42:20 |
| User entered '0' | Mikayla Frye (b) (4) (b) (4) | 14 Aug 2020 20:09:48 |

US3552035

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:49:48

Start Month and Year (derived)

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:36:03 |
| User entered 'Jan 2010' | System | 14 Aug 2020 20:09:48 |

US3552035

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:49:48

Start Year (derived)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:36:03 |
| User entered '2010' | System | 14 Aug 2020 20:09:48 |

US3552035

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:49:48

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:36:03 |
| User entered empty. | System | 14 Aug 2020 20:09:48 |

US3552035

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:49:48

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:36:03 |
| User entered empty. | System | 14 Aug 2020 20:09:48 |

US3552035

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:49:48

Condition

| Audit | User | Time (GMT) |
|---|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:36:03 |
| User signature succeeded. | sharon trey (b) (4) (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 27 Oct 2020 22:04:02 |
| User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Herpes viral infections, PT: Herpes zoster, LLT: Shingles - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 17 Sep 2020 20:17:40 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 17 Sep 2020 20:17:40 |
| Data point term sent to Coder | System | 17 Sep 2020 20:16:52 |
| User entered 'shingles' | Joan Siegner (b) (4) (b) (4) | 17 Sep 2020 20:16:16 |

US3552035

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:49:48

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

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:36:03 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 27 Oct 2020 22:04:04 |
| User entered 'un Oct 2017' | Joan Siegner (b) (4) [REDACTED] | 17 Sep 2020 20:16:16 |

US3552035

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:49:48

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:36:03 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 27 Oct 2020 22:04:05 |
| User entered '0' | Joan Siegner (b) (4) [REDACTED] | 17 Sep 2020 20:16:16 |

US3552035

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:49:48

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:36:03 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 27 Oct 2020 22:04:07 |
| User entered 'No (N)' | Joan Siegner (b) (4) [REDACTED] | 17 Sep 2020 20:16:16 |

US3552035

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:49:48

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

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:36:03 |
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) | 27 Oct 2020 22:04:09 |
| User entered 'un Nov 2017' | Joan Siegner (b) (4) | 17 Sep 2020 20:16:16 |

US3552035

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:49:48

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:36:03 |
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) | 27 Oct 2020 22:04:11 |
| User entered '0' | (b) (4), (b) (6) | 27 Oct 2020 22:04:11 |
| | Joan Siegner (b) (4) | 17 Sep 2020 20:16:16 |
| | | |

US3552035

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:49:48

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:36:03 |
| User entered 'Oct 2017' | System | 17 Sep 2020 20:16:16 |

US3552035

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:49:48

Start Year (derived)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:36:03 |
| User entered '2017' | System | 17 Sep 2020 20:16:16 |

US3552035

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:49:48

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:36:03 |
| User entered 'Nov 2017' | System | 17 Sep 2020 20:16:16 |

US3552035

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:49:48

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:36:03 |
| User entered '2017' | System | 17 Sep 2020 20:16:16 |

US3552035

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:49:48

[Condition](#)

| Audit | User | Time (GMT) |
|---|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:36:03 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 27 Oct 2020 22:04:15 |
| User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Back pain, LLT: Back pain - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 09 Oct 2020 00:00:58 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 09 Oct 2020 00:00:58 |
| Data point term sent to Coder | System | 08 Oct 2020 19:22:01 |
| User entered 'back pain' | Stanley Dublin (b) (4) (b) (4) | 08 Oct 2020 19:21:40 |

US3552035

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:49:48

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

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:36:03 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 27 Oct 2020 22:04:16 |
| User entered 'un Oct 2017' | Stanley Doublin (b) (4) (b) (4) | 08 Oct 2020 19:21:40 |

US3552035

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:49:48

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:36:03 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 27 Oct 2020 22:04:18 |
| User entered '0' | Stanley Doublin (b) (4) (b) (4) | 08 Oct 2020 19:21:40 |

US3552035

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:49:48

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:36:03 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 27 Oct 2020 22:04:20 |
| User entered 'Yes (Y)' | Stanley Doublin (b) (4) (b) (4) | 08 Oct 2020 19:21:40 |

US3552035

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:49:48

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:36:03 |
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 27 Oct 2020 22:04:21 |
| User entered empty. | Stanley Dublin (b) (4) | 08 Oct 2020 19:21:40 |

US3552035

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:49:48

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:36:03 |
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) | 27 Oct 2020 22:04:23 |
| User entered '0' | (b) (4), (b) (6) | 27 Oct 2020 22:04:23 |
| | Stanley Doublin (b) (4) | 08 Oct 2020 19:21:40 |
| | (b) (4) | |

US3552035

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:49:48

Start Month and Year (derived)

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:36:03 |
| User entered 'Oct 2017' | System | 08 Oct 2020 19:21:40 |

US3552035

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:49:48

Start Year (derived)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:36:03 |
| User entered '2017' | System | 08 Oct 2020 19:21:40 |

US3552035

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:49:48

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:36:03 |
| User entered empty. | System | 08 Oct 2020 19:21:40 |

US3552035

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:49:48

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:36:03 |
| User entered empty. | System | 08 Oct 2020 19:21:40 |

US3552035

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:49:48

Condition

| Audit | User | Time (GMT) |
|---|--------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:36:03 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:31:36 |
| User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders), HLT: Intervertebral disc disorders NEC, PT: Intervertebral disc degeneration, LLT: Lumbar disc degeneration - version MedDRA\23.0. | Coder Import (b) (4) (b) (4) | 17 Nov 2020 08:20:54 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0. | Coder Import (b) (4) (b) (4) | 17 Nov 2020 08:20:54 |
| User closed query 'Please add that it is L4-5 to reconcile with source Thank you!' (Site from CRA). | (b) (4), (b) (6) | 27 Oct 2020 22:04:29 |
| DataPoint Verified. | | 27 Oct 2020 22:04:28 |
| Data point term sent to Coder | | 27 Oct 2020 15:39:31 |
| Query 'Please add that it is L4-5 to reconcile with source Thank you!' answered with 'updated per query request' (Site from CRA). | Cassandra Zehenny (b) (4) (b) (4) | 27 Oct 2020 15:39:18 |
| DataPoint Un-verified. | Cassandra Zehenny (b) (4) (b) (4) | 27 Oct 2020 15:38:53 |
| Coding entries removed. | Cassandra Zehenny (b) (4) (b) (4) | 27 Oct 2020 15:38:53 |
| User entered 'L4-L5 DEGENERATIVE DISK' reason for change: Per Query Resolution | Cassandra Zehenny (b) (4) (b) (4) | 27 Oct 2020 15:38:53 |
| User closed query 'Per DM CLR: Please specify the location (bilateral, left, right) and/or type of DEGENERATIVE DISK. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM). | (b) (4), (b) (6) | 27 Oct 2020 10:06:02 |
| User opened query 'Please add that it is L4-5 to reconcile with source Thank you!' (Site from CRA). | | 26 Oct 2020 19:17:02 |
| DataPoint Verified. | | 26 Oct 2020 19:11:53 |

US3552035

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:49:48

[Condition](#)

| Audit | User | Time (GMT) |
|---|-------------------------|----------------------|
| Query 'Per DM CLR: Please specify the location (bilateral, left, right) and/or type of DEGENERATIVE DISK. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' answered with 'Unknown, medical records not available as we are not a clinical site. Con meds within 28 days of 1st vaccination are recorded as per protocol.' (Site from DM). | Heather Douds (b) (4) | 23 Oct 2020 14:27:44 |
| User opened query 'Per DM CLR: Please specify the location (bilateral, left, right) and/or type of DEGENERATIVE DISK. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM). | (b) (4), (b) (6) | 22 Oct 2020 20:49:44 |
| User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders), HLT: Intervertebral disc disorders NEC, PT: Intervertebral disc degeneration, LLT: Degenerative disc disease - version MedDRA\23.0. | Coder Import (b) (4) | 12 Oct 2020 19:02:20 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0. | Coder Import (b) (4) | 12 Oct 2020 19:02:20 |
| Data point term sent to Coder | System | 12 Oct 2020 19:01:11 |
| User entered 'degenerative disk' | Stanley Doublin (b) (4) | 12 Oct 2020 19:00:59 |

US3552035

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:49:48

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

| Audit | User | Time (GMT) |
|----------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:36:03 |
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Oct 2020 19:15:31 |
| User entered 'un UNK 2001' | Stanley Doublin (b) (4) | 12 Oct 2020 19:00:59 |

US3552035

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:49:48

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:36:03 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Oct 2020 19:15:51 |
| User entered '0' | Stanley Doublin (b) (4) (b) (4) | 12 Oct 2020 19:00:59 |

US3552035

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:49:48

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:36:03 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Oct 2020 19:15:54 |
| User entered 'Yes (Y)' | Stanley Doublin (b) (4) (b) (4) | 12 Oct 2020 19:00:59 |

US3552035

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:49:48

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:36:03 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Oct 2020 19:15:56 |
| User entered empty. | Stanley Dublin (b) (4) (b) (4) | 12 Oct 2020 19:00:59 |

US3552035

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:49:48

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:36:03 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Oct 2020 19:15:57 |
| User entered '0' | Stanley Doublin (b) (4) (b) (4) | 12 Oct 2020 19:00:59 |

US3552035

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:49:48

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:36:03 |
| User entered 'Jan 2001' | System | 12 Oct 2020 19:00:59 |

US3552035

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:49:48

Start Year (derived)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:36:03 |
| User entered '2001' | System | 12 Oct 2020 19:00:59 |

US3552035

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:49:48

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:36:03 |
| User entered empty. | System | 12 Oct 2020 19:00:59 |

US3552035

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:49:48

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:36:03 |
| User entered empty. | System | 12 Oct 2020 19:00:59 |

US3552035

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:48

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:36:03 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Aug 2020 17:42:56 |
| User entered 'Yes (Y)' | Mikayla Frye (b) (4) (b) (4) | 14 Aug 2020 20:10:42 |

US3552035

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:48

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:36:03 |
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 19 Aug 2020 17:42:56 |
| User entered '14 Aug 2020' | Mikayla Frye (b) (4) | 14 Aug 2020 20:10:42 |
| | (b) (4) | |

US3552035

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:48

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

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:36:03 |
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Aug 2020 17:42:56 |
| User entered '10:54' | Mikayla Frye (b) (4) | 14 Aug 2020 20:10:42 |

US3552035

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:48

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:36:03 |
| User entered '14 Aug 2020 10:54' | System | 14 Aug 2020 20:10:42 |

US3552035

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:48

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

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:36:03 |
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 19 Aug 2020 17:42:56 |
| User entered '73' in | Mikayla Frye (b) (4) | 14 Aug 2020 20:10:42 |
| DataPoint set to visible. | (b) (4) | |
| | System | 14 Aug 2020 17:04:33 |

US3552035

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:48

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

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:36:03 |
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 19 Aug 2020 17:42:56 |
| User entered '216' lb | Mikayla Frye (b) (4) | 14 Aug 2020 20:10:42 |
| DataPoint set to visible. | (b) (4) | |
| | System | 14 Aug 2020 17:04:33 |

US3552035

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:48

BMI (xxx.x)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:36:03 |
| Amendment Manager: User entered '28.55735' | System | 16 Sep 2020 23:57:28 |
| User entered '28.6' | System | 14 Aug 2020 20:10:42 |
| DataPoint set to visible. | System | 14 Aug 2020 17:04:33 |

US3552035

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:48

[BMI units](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:36:03 |
| User entered 'kg/m2' | System | 14 Aug 2020 20:10:42 |
| DataPoint set to visible. | System | 14 Aug 2020 17:04:33 |

US3552035

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:48

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:36:03 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Aug 2020 17:42:56 |
| User entered missing code ND - Not Done. | Mikayla Frye (b) (4) (b) (4) | 14 Aug 2020 20:10:42 |

US3552035

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:48

[Route of measurement](#)

| Audit | User | Time (GMT) |
|---|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:36:03 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Aug 2020 17:42:56 |
| User closed query 'Data is required. Please provide.' (Site from System). | | 19 Aug 2020 11:28:24 |
| Query 'Data is required. Please provide.' answered with 'ND' (Site from System). | Mikayla Frye (b) (4) (b) (4) | 14 Aug 2020 20:10:46 |
| User opened query 'Data is required. Please provide.' (Site from System). | System | 14 Aug 2020 20:10:42 |
| User entered empty. | Mikayla Frye (b) (4) (b) (4) | 14 Aug 2020 20:10:42 |

US3552035

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:48

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:36:03 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Aug 2020 17:42:56 |
| User entered empty. | Mikayla Frye (b) (4) (b) (4) | 14 Aug 2020 20:10:42 |

US3552035

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:48

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:36:03 |
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Aug 2020 17:42:56 |
| User entered missing code ND - Not Done. | Mikayla Frye (b) (4) | 14 Aug 2020 20:10:42 |

US3552035

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:48

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:36:03 |
| User entered 'bpm' | System | 14 Aug 2020 20:10:42 |

US3552035

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:48

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

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:36:03 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Aug 2020 17:42:56 |
| User entered missing code ND - Not Done. | Mikayla Frye (b) (4) (b) (4) | 14 Aug 2020 20:10:42 |

US3552035

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:48

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:36:03 |
| User entered 'breaths/min' | System | 14 Aug 2020 20:10:42 |

US3552035

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:48

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:36:03 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Aug 2020 17:42:56 |
| User entered missing code ND - Not Done. | Mikayla Frye (b) (4) (b) (4) | 14 Aug 2020 20:10:42 |

US3552035

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:48

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:36:03 |
| User entered 'mmHg' | System | 14 Aug 2020 20:10:42 |

US3552035

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:48

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:36:03 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Aug 2020 17:42:56 |
| User entered missing code ND - Not Done. | Mikayla Frye (b) (4) (b) (4) | 14 Aug 2020 20:10:42 |

US3552035

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:48

Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:36:03 |
| User entered 'mmHg' | System | 14 Aug 2020 20:10:42 |

US3552035

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:48

[Height \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:36:03 |

US3552035

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:48

Weight (derived)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:36:03 |

US3552035

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:49:48

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:36:03 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Aug 2020 17:43:54 |
| User entered 'Yes (Y)' | Mikayla Frye (b) (4) (b) (4) | 14 Aug 2020 20:10:56 |

US3552035

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:49:48

Date of examination (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:36:03 |
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 19 Aug 2020 17:43:54 |
| User entered '14 Aug 2020' | Mikayla Frye (b) (4) | 14 Aug 2020 20:10:56 |
| | (b) (4) | |

US3552035

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:49:48

[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 18:36:03 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Aug 2020 17:44:39 |
| User entered 'No (N)' | Mikayla Frye (b) (4) (b) (4) | 14 Aug 2020 20:11:49 |

US3552035

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:49:48

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 18:36:03 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Aug 2020 17:44:39 |
| User entered 'No (N)' | Mikayla Frye (b) (4) (b) (4) | 14 Aug 2020 20:11:49 |

US3552035

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:49:48

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 18:36:03 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Aug 2020 17:44:39 |
| User entered 'Yes (Y)' | Mikayla Frye (b) (4) (b) (4) | 14 Aug 2020 20:11:49 |

US3552035

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:49:48

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 18:36:03 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Aug 2020 17:44:39 |
| User entered 'No (N)' | Mikayla Frye (b) (4) (b) (4) | 14 Aug 2020 20:11:49 |

US3552035

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:49:48

[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 18:36:03 |
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Aug 2020 17:44:39 |
| User entered 'No (N)' | Mikayla Frye (b) (4) (b) (4) | 14 Aug 2020 20:11:49 |

US3552035

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:49:48

[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 18:36:03 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Aug 2020 17:44:39 |
| User entered 'No (N)' | Mikayla Frye (b) (4) (b) (4) | 14 Aug 2020 20:11:49 |

US3552035

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:49:48

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 18:36:03 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Aug 2020 17:44:39 |
| User entered 'No (N)' | Mikayla Frye (b) (4) (b) (4) | 14 Aug 2020 20:11:49 |

US3552035

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:49:48

[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 18:36:03 |
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Aug 2020 17:44:39 |
| User entered 'No (N)' | Mikayla Frye (b) (4) (b) (4) | 14 Aug 2020 20:11:49 |

US3552035

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:49:48

[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 18:36:03 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Aug 2020 17:44:39 |
| User entered 'No (N)' | Mikayla Frye (b) (4) (b) (4) | 14 Aug 2020 20:11:49 |

US3552035

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:49:48

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 18:36:03 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Aug 2020 17:44:39 |
| User entered 'No (N)' | Mikayla Frye (b) (4) (b) (4) | 14 Aug 2020 20:11:49 |

US3552035

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:49:48

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 18:36:03 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Aug 2020 17:44:39 |
| User entered 'No (N)' | Mikayla Frye (b) (4) (b) (4) | 14 Aug 2020 20:11:49 |

US3552035

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:49:48

[Other](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:36:03 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Aug 2020 17:44:39 |
| User entered 'No (N)' | Mikayla Frye (b) (4) (b) (4) | 14 Aug 2020 20:11:49 |

US3552035

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:49:48

[Specify](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:36:03 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Aug 2020 17:44:39 |
| User entered empty. | Mikayla Frye (b) (4) (b) (4) | 14 Aug 2020 20:11:49 |

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:49:48

No Risk Identified

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:36:03 |
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| User entered '0' | (b) (4) Mikayla Frye (b) (4) (b) (4) | 14 Aug 2020 20:11:49 |

US3552035

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:49:48

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

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:36:03 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Aug 2020 17:44:39 |
| User entered '0' | Mikayla Frye (b) (4) (b) (4) | 14 Aug 2020 20:11:49 |

US3552035

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:49:48

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 18:36:03 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Aug 2020 17:44:39 |
| User entered '0' | Mikayla Frye (b) (4) (b) (4) | 14 Aug 2020 20:11:49 |

US3552035

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:49:48

[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 18:36:03 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Aug 2020 17:44:39 |
| User entered '0' | Mikayla Frye (b) (4) (b) (4) | 14 Aug 2020 20:11:49 |

US3552035

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:49:48

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 18:36:03 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Aug 2020 17:44:39 |
| User entered '0' | Mikayla Frye (b) (4) (b) (4) | 14 Aug 2020 20:11:49 |

US3552035

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:49:48

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

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:36:03 |
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 19 Aug 2020 17:44:39 |
| User entered 'l' | Mikayla Frye (b) (4) | 14 Aug 2020 20:11:49 |
| | (b) (4) | |

US3552035

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:49:48

Other

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:36:03 |
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| User entered '0' | (b) (4) Mikayla Frye (b) (4) (b) (4) | 14 Aug 2020 20:11:49 |

US3552035

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:49:48

[Specify](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:36:03 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Aug 2020 17:44:39 |
| User entered empty. | Mikayla Frye (b) (4) (b) (4) | 14 Aug 2020 20:11:49 |

US3552035

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:49:48

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:32:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Aug 2020 17:45:10 |
| User entered 'Yes (Y)' | Mikayla Frye (b) (4) (b) (4) | 14 Aug 2020 20:12:00 |

US3552035

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:49:48

Visit date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:32:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Aug 2020 17:45:10 |
| User entered '14 Aug 2020' | Mikayla Frye (b) (4) (b) (4) | 14 Aug 2020 20:12:00 |

US3552035

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:49:48

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

| Audit | User | Time (GMT) |
|--------------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:32:03 |
| DataPoint Verified. | (b) (4) | 19 Aug 2020 17:45:10 |
| User entered 'Clinic (Clinic)' | (b) (4), (b) (6) | 19 Aug 2020 17:45:10 |
| | Mikayla Frye (b) (4) | 14 Aug 2020 20:12:00 |
| | (b) (4) | |

US3552035

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:49:48

[Folder OID](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User entered 'VISIT1' | System | 14 Aug 2020 20:12:00 |

US3552035

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:49:48

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

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:32:03 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 19 Aug 2020 17:45:24 |
| User entered '14 AUG 2020' | RWS_ENDPOINT ENDPOINT (b) (4) | 14 Aug 2020 16:54:57 |

US3552035

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:49:48

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

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:32:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Oct 2020 19:17:29 |
| Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System). | System | 21 Aug 2020 04:35:29 |
| Amendment Manager: Data point set to conformant. | System | 21 Aug 2020 04:35:28 |
| User opened query 'Data entered is non-conformant. Please correct.' (Site from System). | System | 14 Aug 2020 16:54:57 |
| User entered '104082' (non-conformant). | RWS_ENDPOINT ENDPOINT (b) (4) | 14 Aug 2020 16:54:57 |

US3552035

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:49:48

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

| Audit | User | Time (GMT) |
|---|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:32:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Aug 2020 17:45:25 |
| User entered '>=18 and <65 years and not at risk (1)' | RWS_ENDPOINT ENDPOINT (b) (4) | 14 Aug 2020 16:54:57 |

US3552035

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:49:48

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) | 28 Mar 2021 08:53:51 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:32:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Aug 2020 17:45:27 |
| User entered 'No (N)' | Mikayla Frye (b) (4) (b) (4) | 14 Aug 2020 20:12:17 |

US3552035

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:49:48

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) | 28 Mar 2021 08:53:51 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:32:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Aug 2020 17:45:30 |
| User entered 'No (N)' | Mikayla Frye (b) (4) (b) (4) | 14 Aug 2020 20:12:17 |

US3552035

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:49:48

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

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:32:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Aug 2020 17:45:32 |
| User entered 'No (N)' | Mikayla Frye (b) (4) (b) (4) | 14 Aug 2020 20:12:17 |

US3552035

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:49:48

[Diabetes \(Type I, Type 2, or gestational\)](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:32:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Aug 2020 17:45:34 |
| User entered 'No (N)' | Mikayla Frye (b) (4) (b) (4) | 14 Aug 2020 20:12:17 |

US3552035

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:49:48

[Liver Disease](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:32:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Aug 2020 17:45:36 |
| User entered 'No (N)' | Mikayla Frye (b) (4) (b) (4) | 14 Aug 2020 20:12:17 |

US3552035

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:49:48

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

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:32:03 |
| DataPoint Verified. | (b) (4) | 26 Oct 2020 19:17:31 |
| User entered 'No (N)' | (b) (4), (b) (6) | 26 Oct 2020 19:17:31 |
| | Stanley Doublin (b) (4) | 21 Sep 2020 17:00:36 |
| | (b) (4) | |
| Amendment Manager: DataPoint set to visible. | System | 19 Sep 2020 10:21:09 |
| Amendment Manager inserted this DataPoint. | System | 19 Sep 2020 07:19:46 |

US3552035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:49:48

[Height](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:32:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Aug 2020 17:46:34 |
| User entered missing code ND - Not Done. | Mikayla Frye (b) (4) (b) (4) | 14 Aug 2020 20:14:02 |

US3552035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:49:48

[Weight](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:32:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Aug 2020 17:46:34 |
| User entered missing code ND - Not Done. | Mikayla Frye (b) (4) (b) (4) | 14 Aug 2020 20:14:02 |

US3552035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:49:48

[Height](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:32:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Aug 2020 17:46:34 |
| User entered missing code ND - Not Done. | Mikayla Frye (b) (4) (b) (4) | 14 Aug 2020 20:14:02 |

US3552035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:49:48

[Weight](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:32:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Aug 2020 17:46:34 |
| User entered missing code ND - Not Done. | Mikayla Frye (b) (4) (b) (4) | 14 Aug 2020 20:14:02 |

US3552035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:48

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User accepted default value 'Pre-Dose (PREDOSE)' | Mikayla Frye (b) (4) (b) (4) | 14 Aug 2020 20:14:02 |

US3552035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:48

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:32:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Aug 2020 17:46:34 |
| User entered 'Yes (Y)' | Mikayla Frye (b) (4) (b) (4) | 14 Aug 2020 20:14:02 |

US3552035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:48

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:32:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Aug 2020 17:46:34 |
| User entered '14 Aug 2020' | Mikayla Frye (b) (4) (b) (4) | 14 Aug 2020 20:14:02 |

US3552035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:48

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

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:32:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Aug 2020 17:46:34 |
| User entered '10:54' | Mikayla Frye (b) (4) (b) (4) | 14 Aug 2020 20:14:02 |

US3552035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:48

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User entered '14 Aug 2020 10:54' | System | 14 Aug 2020 20:14:02 |

US3552035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:48

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:32:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Aug 2020 17:46:34 |
| User entered '97.8' F | Mikayla Frye (b) (4) (b) (4) | 14 Aug 2020 20:14:02 |

US3552035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:48

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:32:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Aug 2020 17:46:34 |
| User entered 'Oral (Oral)' | Mikayla Frye (b) (4) (b) (4) | 14 Aug 2020 20:14:02 |

US3552035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:48

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:32:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Aug 2020 17:46:34 |
| User entered empty. | Mikayla Frye (b) (4) (b) (4) | 14 Aug 2020 20:14:02 |

US3552035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:48

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:32:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Aug 2020 17:46:34 |
| User entered '68' | Mikayla Frye (b) (4) (b) (4) | 14 Aug 2020 20:14:02 |

US3552035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:48

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User entered 'bpm' | System | 14 Aug 2020 20:14:02 |

US3552035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:48

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

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:32:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Aug 2020 17:46:34 |
| User entered '18' | Mikayla Frye (b) (4) (b) (4) | 14 Aug 2020 20:14:02 |

US3552035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:48

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User entered 'breaths/min' | System | 14 Aug 2020 20:14:02 |

US3552035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:48

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:32:03 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Aug 2020 17:46:34 |
| User entered '127' | Mikayla Frye (b) (4) (b) (4) | 14 Aug 2020 20:14:02 |

US3552035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:48

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User entered 'mmHg' | System | 14 Aug 2020 20:14:02 |

US3552035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:48

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:32:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Aug 2020 17:46:34 |
| User entered '80' | Mikayla Frye (b) (4) (b) (4) | 14 Aug 2020 20:14:02 |

US3552035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:48

Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User entered 'mmHg' | System | 14 Aug 2020 20:14:02 |

US3552035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:49:48

[Height](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:32:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Aug 2020 17:46:34 |
| User entered missing code ND - Not Done. | Mikayla Frye (b) (4) (b) (4) | 14 Aug 2020 20:14:02 |

US3552035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:49:48

[Weight](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:32:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Aug 2020 17:46:34 |
| User entered missing code ND - Not Done. | Mikayla Frye (b) (4) (b) (4) | 14 Aug 2020 20:14:02 |

US3552035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:48

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User accepted default value 'Post-Dose (POSTDOSE)' | Mikayla Frye (b) (4) (b) (4) | 14 Aug 2020 20:14:02 |

US3552035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:48

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:32:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Aug 2020 17:46:34 |
| User entered 'Yes (Y)' | Mikayla Frye (b) (4) (b) (4) | 14 Aug 2020 20:14:02 |

US3552035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:48

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:32:03 |
| DataPoint Verified. | (b) (4) | 19 Aug 2020 17:46:34 |
| User entered '14 Aug 2020' | (b) (4), (b) (6) | 19 Aug 2020 17:46:34 |
| | Mikayla Frye (b) (4) | 14 Aug 2020 20:14:02 |
| | (b) (4) | |

US3552035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:48

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

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:32:03 |
| Amendment Manager: Query closed during migration process because the edit check no longer exists in target version. | System | 21 Aug 2020 04:35:25 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Aug 2020 17:46:34 |
| Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with 'Time is correct as entered.' (Site from System). | Mikayla Frye (b) (4) (b) (4) | 14 Aug 2020 20:14:25 |
| User opened query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System). | System | 14 Aug 2020 20:14:15 |
| User closed query 'Data is required. Please provide.' (Site from System). | System | 14 Aug 2020 20:14:15 |
| Query 'Data is required. Please provide.' answered by System data change (Site from System). | | 14 Aug 2020 20:14:15 |
| User entered '12:53' reason for change: Data Entry Error | Mikayla Frye (b) (4) (b) (4) | 14 Aug 2020 20:14:15 |
| User opened query 'Data is required. Please provide.' (Site from System). | System | 14 Aug 2020 20:14:02 |
| User entered empty. | Mikayla Frye (b) (4) (b) (4) | 14 Aug 2020 20:14:02 |

US3552035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:48

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User entered '14 Aug 2020 12:53' | System | 14 Aug 2020 20:14:15 |
| User entered empty. | System | 14 Aug 2020 20:14:02 |

US3552035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:48

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:32:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Aug 2020 17:46:34 |
| User entered '97.7' F | Mikayla Frye (b) (4) (b) (4) | 14 Aug 2020 20:14:02 |

US3552035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:48

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:32:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Aug 2020 17:46:34 |
| User entered 'Oral (Oral)' | Mikayla Frye (b) (4) (b) (4) | 14 Aug 2020 20:14:02 |

US3552035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:48

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:32:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Aug 2020 17:46:34 |
| User entered empty. | Mikayla Frye (b) (4) (b) (4) | 14 Aug 2020 20:14:02 |

US3552035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:48

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:32:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Aug 2020 17:46:34 |
| User entered '60' | Mikayla Frye (b) (4) (b) (4) | 14 Aug 2020 20:14:02 |

US3552035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:48

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User entered 'bpm' | System | 14 Aug 2020 20:14:02 |

US3552035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:48

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

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:32:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Aug 2020 17:46:34 |
| User entered '20' | Mikayla Frye (b) (4) (b) (4) | 14 Aug 2020 20:14:02 |

US3552035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:48

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User entered 'breaths/min' | System | 14 Aug 2020 20:14:02 |

US3552035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:48

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:32:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Aug 2020 17:46:34 |
| User entered '128' | Mikayla Frye (b) (4) (b) (4) | 14 Aug 2020 20:14:02 |

US3552035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:48

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User entered 'mmHg' | System | 14 Aug 2020 20:14:02 |

US3552035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:48

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:32:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Aug 2020 17:46:34 |
| User entered '77' | Mikayla Frye (b) (4) (b) (4) | 14 Aug 2020 20:14:02 |

US3552035

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:48

Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User entered 'mmHg' | System | 14 Aug 2020 20:14:02 |

US3552035

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:49:48

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Aug 2020 17:46:43 |
| User entered 'No (N)' | Stanley Doublin (b) (4) (b) (4) | 18 Aug 2020 19:07:02 |

US3552035

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:49:48

Date of examination (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Aug 2020 17:46:43 |
| User entered empty. | Stanley Doublin (b) (4) (b) (4) | 18 Aug 2020 19:07:02 |

US3552035

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:49:48

[Was study treatment given?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Aug 2020 17:46:55 |
| User entered 'Yes (Y)' | | 14 Aug 2020 17:26:31 |

US3552035

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:49:48

[If No, reason not given](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) | 19 Aug 2020 17:46:55 |
| User entered empty. | (b) (4), (b) (6) | 14 Aug 2020 17:26:31 |

US3552035

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:49:48

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) | 28 Mar 2021 08:53:51 |
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) | 19 Aug 2020 17:46:55 |
| User entered empty. | (b) (4), (b) (6) | 14 Aug 2020 17:26:31 |

US3552035

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:49:48

[What was the study treatment?](#)

| Audit | User | Time (GMT) |
|-------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User entered 'MRNA-1273 OR PLACEBO' | System | 14 Aug 2020 17:26:31 |

US3552035

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:49:48

What was the treatment date? (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 19 Aug 2020 17:46:55 |
| User entered '14 Aug 2020' | | 14 Aug 2020 17:26:31 |

US3552035

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:49:48

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

| Audit | User | Time (GMT) |
|---------------------------|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) | 19 Aug 2020 17:46:55 |
| User entered '12:23' | (b) (4), (b) (6) | 14 Aug 2020 17:26:31 |

US3552035

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:49:48

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User entered '14 Aug 2020 12:23' | System | 14 Aug 2020 17:26:31 |

US3552035

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:49:48

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

| Audit | User | Time (GMT) |
|------------------------------------|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) | 19 Aug 2020 17:46:55 |
| User entered 'Left Arm (LEFT ARM)' | (b) (4), (b) (6) | 14 Aug 2020 17:26:31 |

US3552035

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:49:48

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| DataPoint Verified. | | 19 Aug 2020 17:46:55 |
| User entered 'ONCE' | System | 14 Aug 2020 17:26:31 |

US3552035

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:49:48

What was the route of administration for the study treatment?

| Audit | User | Time (GMT) |
|------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User entered 'INTRAMUSCULAR' | System | 14 Aug 2020 17:26:31 |

US3552035

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:49:48

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Aug 2020 17:47:07 |
| User entered 'Yes (Y)' | Mikayla Frye (b) (4) (b) (4) | 14 Aug 2020 20:14:45 |

US3552035

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:49:48

Collection date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Aug 2020 17:47:07 |
| User entered '14 Aug 2020' | Mikayla Frye (b) (4) (b) (4) | 14 Aug 2020 20:14:45 |

US3552035

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:49:48

Collection time (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Aug 2020 17:47:07 |
| User entered '11:28' | Mikayla Frye (b) (4) (b) (4) | 14 Aug 2020 20:14:45 |

US3552035

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:49:48

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User entered '14 Aug 2020 11:28' | System | 14 Aug 2020 20:14:45 |

US3552035

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:49:48

Collection date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Aug 2020 17:47:18 |
| User entered '14 Aug 2020' | Mikayla Frye (b) (4) (b) (4) | 14 Aug 2020 20:14:59 |

US3552035

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:49:48

[Lab Test](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)' | Mikayla Frye (b) (4) (b) (4) | 14 Aug 2020 20:14:59 |

US3552035

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:49:48

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Aug 2020 17:47:18 |
| User entered 'Yes (Y)' | Mikayla Frye (b) (4) (b) (4) | 14 Aug 2020 20:14:59 |

US3552035

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:49:48

Collection time (00:00 - 23:59)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) | 19 Aug 2020 17:47:18 |
| User entered '11:33' | (b) (4), (b) (6) | 19 Aug 2020 17:47:18 |
| | Mikayla Frye (b) (4) | 14 Aug 2020 20:14:59 |
| | (b) (4) | |

US3552035

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:49:48

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User entered '14 Aug 2020 11:33' | System | 14 Aug 2020 20:14:59 |

US3552035

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:49:48

[Lab Test](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)' | Mikayla Frye (b) (4) (b) (4) | 14 Aug 2020 20:14:59 |

US3552035

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:49:48

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 19 Aug 2020 17:47:18 |
| User entered 'No (N)' | Mikayla Frye (b) (4) (b) (4) | 14 Aug 2020 20:14:59 |

US3552035

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:49:48

Collection time (00:00 - 23:59)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 19 Aug 2020 17:47:18 |
| User entered empty. | Mikayla Frye (b) (4) (b) (4) | 14 Aug 2020 20:14:59 |

US3552035

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:49:48

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User entered empty. | System | 14 Aug 2020 20:14:59 |

US3552035

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:49:48

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Oct 2020 17:48:22 |
| User entered 'Yes (Y)' | Mikayla Frye (b) (4) (b) (4) | 21 Aug 2020 20:35:07 |

US3552035

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:49:48

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User entered 'l' | System | 21 Aug 2020 20:35:07 |

US3552035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:49:48

TIMEPOINT

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| Data entry locked. | System | 14 Aug 2020 17:26:31 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 14 Aug 2020 17:26:31 |

US3552035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:49:48

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-14T13:03:37', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'e2ac06c3-5363-44e3-b25f-9372daee10c7' User entered 'Yes (Y)' | System | 14 Aug 2020 18:04:03 |
| | System | 14 Aug 2020 18:04:03 |

US3552035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:49:48

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-14T13:03:47', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'e2ac06c3-5363-44e3-b25f-9372daee10c7' User entered '97.7' | System | 14 Aug 2020 18:04:03 |
| | System | 14 Aug 2020 18:04:03 |

US3552035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:49:48

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-14T13:03:50', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'e2ac06c3-5363-44e3-b25f-9372daee10c7' User entered 'No (N)' | System | 14 Aug 2020 18:04:03 |
| | System | 14 Aug 2020 18:04:03 |

US3552035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:49:48

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-14T13:03:58', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'e2ac06c3-5363-44e3-b25f-9372daee10c7' User entered '14 Aug 2020 13:03' | System | 14 Aug 2020 18:04:03 |
| | System | 14 Aug 2020 18:04:03 |

US3552035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:49:48

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| User entered '14 Aug 2020 12:43' | System | 14 Aug 2020 17:26:31 |

US3552035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:49:48

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| User entered '14 Aug 2020 15:13' | System | 14 Aug 2020 17:26:31 |

US3552035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:49:48

TIMEPOINT

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| Data entry locked. | System | 14 Aug 2020 17:26:31 |
| User entered 'Day 1, after vaccination (at home)' | System | 14 Aug 2020 17:26:31 |

US3552035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:49:48

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-15T10:42:54', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'ad799a5e-0b49-4670-831e-0669a4363522' User entered 'Yes (Y)' | System | 15 Aug 2020 15:44:03 |
| | System | 15 Aug 2020 15:44:03 |

US3552035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:49:48

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-15T10:43:06', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'ad799a5e-0b49-4670-831e-0669a4363522' User entered '96.8' | System | 15 Aug 2020 15:44:03 |
| | System | 15 Aug 2020 15:44:03 |

US3552035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:49:48

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-15T10:43:12', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'ad799a5e-0b49-4670-831e-0669a4363522' | System | 15 Aug 2020 15:44:03 |
| User entered 'No (N)' | System | 15 Aug 2020 15:44:03 |

US3552035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:49:48

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-15T10:44:01', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'ad799a5e-0b49-4670-831e-0669a4363522' User entered '15 Aug 2020 10:44' | System | 15 Aug 2020 15:44:03 |
| | System | 15 Aug 2020 15:44:03 |

US3552035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:49:48

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| User entered '14 Aug 2020 16:08' | System | 14 Aug 2020 17:26:31 |

US3552035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:49:48

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| User entered '15 Aug 2020 11:59' | System | 14 Aug 2020 17:26:31 |

US3552035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:49:48

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| Data entry locked. | System | 14 Aug 2020 17:26:31 |
| User entered 'Day 2' | System | 14 Aug 2020 17:26:31 |

US3552035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:49:48

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-16T00:22:59', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '0601e31d-9a95-48e1-90df-d06d132a1b1f' User entered 'Yes (Y)' | System | 16 Aug 2020 05:23:22 |
| | System | 16 Aug 2020 05:23:22 |

US3552035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:49:48

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-16T00:23:14', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '0601e31d-9a95-48e1-90df-d06d132a1b1f' User entered '97.4' | System | 16 Aug 2020 05:23:22 |
| | System | 16 Aug 2020 05:23:22 |

US3552035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:49:48

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-16T00:23:17', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '0601e31d-9a95-48e1-90df-d06d132a1b1f' User entered 'No (N)' | System | 16 Aug 2020 05:23:22 |
| | System | 16 Aug 2020 05:23:22 |

US3552035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:49:48

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-16T00:23:21', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '0601e31d-9a95-48e1-90df-d06d132a1b1f' User entered '16 Aug 2020 00:23' | System | 16 Aug 2020 05:23:22 |
| | System | 16 Aug 2020 05:23:22 |

US3552035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:49:48

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| User entered '15 Aug 2020 12:00' | System | 14 Aug 2020 17:26:31 |

US3552035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:49:48

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| User entered '16 Aug 2020 11:59' | System | 14 Aug 2020 17:26:31 |

US3552035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:49:48

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| Data entry locked. | System | 14 Aug 2020 17:26:31 |
| User entered 'Day 3' | System | 14 Aug 2020 17:26:31 |

US3552035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:49:48

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-16T22:41:56', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'c9ff5cb6-d317-4859-a985-90b72802a044' User entered 'Yes (Y)' | System | 17 Aug 2020 03:43:05 |
| | System | 17 Aug 2020 03:43:05 |

US3552035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:49:48

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-16T22:42:56', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'c9ff5cb6-d317-4859-a985-90b72802a044' User entered '97.7' | System | 17 Aug 2020 03:43:05 |
| | System | 17 Aug 2020 03:43:05 |

US3552035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:49:48

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-16T22:42:59', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'c9ff5cb6-d317-4859-a985-90b72802a044' | System | 17 Aug 2020 03:43:05 |
| User entered 'No (N)' | System | 17 Aug 2020 03:43:05 |

US3552035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:49:48

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-16T22:43:01', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'c9ff5cb6-d317-4859-a985-90b72802a044' | System | 17 Aug 2020 03:43:05 |
| User entered '16 Aug 2020 22:43' | System | 17 Aug 2020 03:43:05 |

US3552035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:49:48

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| User entered '16 Aug 2020 12:00' | System | 14 Aug 2020 17:26:31 |

US3552035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:49:48

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| User entered '17 Aug 2020 11:59' | System | 14 Aug 2020 17:26:31 |

US3552035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:49:48

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| Data entry locked. | System | 14 Aug 2020 17:26:31 |
| User entered 'Day 4' | System | 14 Aug 2020 17:26:31 |

US3552035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:49:48

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-18T02:09:11', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '08870f86-e5cb-439b-a412-d58be6d4b212' User entered 'Yes (Y)' | System | 18 Aug 2020 07:13:00 |
| | System | 18 Aug 2020 07:13:00 |

US3552035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:49:48

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-18T02:12:49', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '08870f86-e5cb-439b-a412-d58be6d4b212' User entered '96.9' | System | 18 Aug 2020 07:13:00 |
| | System | 18 Aug 2020 07:13:00 |

US3552035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:49:48

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-18T02:12:53', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '08870f86-e5cb-439b-a412-d58be6d4b212' | System | 18 Aug 2020 07:13:00 |
| User entered 'No (N)' | System | 18 Aug 2020 07:13:00 |

US3552035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:49:48

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-18T02:12:56', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '08870f86-e5cb-439b-a412-d58be6d4b212' User entered '18 Aug 2020 02:12' | System | 18 Aug 2020 07:13:00 |
| | System | 18 Aug 2020 07:13:00 |

US3552035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:49:48

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| User entered '17 Aug 2020 12:00' | System | 14 Aug 2020 17:26:31 |

US3552035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:49:48

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| User entered '18 Aug 2020 11:59' | System | 14 Aug 2020 17:26:31 |

US3552035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:49:48

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| Data entry locked. | System | 14 Aug 2020 17:26:31 |
| User entered 'Day 5' | System | 14 Aug 2020 17:26:31 |

US3552035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:49:48

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-19T00:55:15', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '37dbf7ed-50b8-49fb-9b69-1bdd640d525c' User entered 'Yes (Y)' | System | 19 Aug 2020 05:55:58 |
| | System | 19 Aug 2020 05:55:58 |

US3552035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:49:48

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-19T00:55:47', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '37dbf7ed-50b8-49fb-9b69-1bdd640d525c' User entered '97.6' | System | 19 Aug 2020 05:55:58 |
| | System | 19 Aug 2020 05:55:58 |

US3552035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:49:48

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-19T00:55:50', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '37dbf7ed-50b8-49fb-9b69-1bdd640d525c' User entered 'No (N)' | System | 19 Aug 2020 05:55:58 |
| | System | 19 Aug 2020 05:55:58 |

US3552035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:49:48

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-19T00:55:53', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '37dbf7ed-50b8-49fb-9b69-1bdd640d525c' User entered '19 Aug 2020 00:55' | System | 19 Aug 2020 05:55:58 |
| | System | 19 Aug 2020 05:55:58 |

US3552035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:49:48

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| User entered '18 Aug 2020 12:00' | System | 14 Aug 2020 17:26:31 |

US3552035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:49:48

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| User entered '19 Aug 2020 11:59' | System | 14 Aug 2020 17:26:31 |

US3552035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:49:48

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| Data entry locked. | System | 14 Aug 2020 17:26:31 |
| User entered 'Day 6' | System | 14 Aug 2020 17:26:31 |

US3552035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:49:48

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-20T02:34:57', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '960a4424-f519-46e8-8536-c0079b5caad9' User entered 'Yes (Y)' | System | 20 Aug 2020 07:35:13 |
| | System | 20 Aug 2020 07:35:13 |

US3552035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:49:48

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-20T02:35:06', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '960a4424-f519-46e8-8536-c0079b5caad9' User entered '97.4' | System | 20 Aug 2020 07:35:13 |
| | System | 20 Aug 2020 07:35:13 |

US3552035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:49:48

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-20T02:35:09', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '960a4424-f519-46e8-8536-c0079b5caad9' | System | 20 Aug 2020 07:35:13 |
| User entered 'No (N)' | System | 20 Aug 2020 07:35:13 |

US3552035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:49:48

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-20T02:35:12', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '960a4424-f519-46e8-8536-c0079b5caad9' User entered '20 Aug 2020 02:35' | System | 20 Aug 2020 07:35:13 |
| | System | 20 Aug 2020 07:35:13 |

US3552035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:49:48

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| User entered '19 Aug 2020 12:00' | System | 14 Aug 2020 17:26:31 |

US3552035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:49:48

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| User entered '20 Aug 2020 11:59' | System | 14 Aug 2020 17:26:31 |

US3552035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:49:48

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| Data entry locked. | System | 14 Aug 2020 17:26:31 |
| User entered 'Day 7' | System | 14 Aug 2020 17:26:31 |

US3552035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:49:48

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-20T23:38:19', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '32dc5965-4eb3-4393-890d-d72f57514ce4' User entered 'Yes (Y)' | System | 21 Aug 2020 04:38:37 |
| | System | 21 Aug 2020 04:38:37 |

US3552035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:49:48

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-20T23:38:27', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '32dc5965-4eb3-4393-890d-d72f57514ce4' User entered '97.1' | System | 21 Aug 2020 04:38:37 |
| | System | 21 Aug 2020 04:38:37 |

US3552035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:49:48

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-20T23:38:31', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '32dc5965-4eb3-4393-890d-d72f57514ce4' | System | 21 Aug 2020 04:38:37 |
| User entered 'No (N)' | System | 21 Aug 2020 04:38:37 |

US3552035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:49:48

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-20T23:38:34', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '32dc5965-4eb3-4393-890d-d72f57514ce4' User entered '20 Aug 2020 23:38' | System | 21 Aug 2020 04:38:37 |
| | System | 21 Aug 2020 04:38:37 |

US3552035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:49:48

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| User entered '20 Aug 2020 12:00' | System | 14 Aug 2020 17:26:31 |

US3552035

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:49:48

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| User entered '21 Aug 2020 11:59' | System | 14 Aug 2020 17:26:31 |

US3552035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:49:48

TIMEPOINT

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| Data entry locked. | System | 14 Aug 2020 17:26:31 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 14 Aug 2020 17:26:31 |

US3552035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:49:48

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-14T13:04:55', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '57eb1508-6e29-4f71-a6d9-b0b75dd1353c' | System | 14 Aug 2020 18:05:37 |
| User entered 'None (1)' | System | 14 Aug 2020 18:05:37 |

US3552035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:49:48

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-14T13:04:58', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '57eb1508-6e29-4f71-a6d9-b0b75dd1353c' User entered 'Yes (Y)' | System | 14 Aug 2020 18:05:37 |
| | System | 14 Aug 2020 18:05:37 |

US3552035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:49:48

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

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-14T13:05:05', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '57eb1508-6e29-4f71-a6d9-b0b75dd1353c' User entered '10' | System | 14 Aug 2020 18:05:37 |
| | System | 14 Aug 2020 18:05:37 |

US3552035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:49:48

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-14T13:05:08', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '57eb1508-6e29-4f71-a6d9-b0b75dd1353c' User entered 'No (N)' | System | 14 Aug 2020 18:05:37 |
| | System | 14 Aug 2020 18:05:37 |

US3552035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:49:48

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-14T13:05:31', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '57eb1508-6e29-4f71-a6d9-b0b75dd1353c' | System | 14 Aug 2020 18:05:37 |
| User entered 'None (1)' | System | 14 Aug 2020 18:05:37 |

US3552035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:49:48

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-14T13:05:34', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '57eb1508-6e29-4f71-a6d9-b0b75dd1353c' User entered '14 Aug 2020 13:05' | System | 14 Aug 2020 18:05:37 |
| | System | 14 Aug 2020 18:05:37 |

US3552035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:49:48

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| User entered '14 Aug 2020 12:43' | System | 14 Aug 2020 17:26:31 |

US3552035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:49:48

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| User entered '14 Aug 2020 15:13' | System | 14 Aug 2020 17:26:31 |

US3552035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:49:48

TIMEPOINT

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| Data entry locked. | System | 14 Aug 2020 17:26:31 |
| User entered 'Day 1, after vaccination (at home)' | System | 14 Aug 2020 17:26:31 |

US3552035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:49:48

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-15T10:44:29', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'd79db794-cac9-44ff-8ff5-ef28a097b2bc' | System | 15 Aug 2020 15:54:36 |
| User entered 'Does not interfere with activity (2)' | System | 15 Aug 2020 15:54:36 |

US3552035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:49:48

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-15T10:52:33', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'd79db794-cac9-44ff-8ff5-ef28a097b2bc' | System | 15 Aug 2020 15:54:36 |
| User entered 'No (N)' | System | 15 Aug 2020 15:54:36 |

US3552035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:49:48

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-15T10:53:30', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'd79db794-cac9-44ff-8ff5-ef28a097b2bc' | System | 15 Aug 2020 15:54:36 |
| User entered 'No (N)' | System | 15 Aug 2020 15:54:36 |

US3552035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:49:48

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-15T10:54:27', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'd79db794-cac9-44ff-8ff5-ef28a097b2bc' | System | 15 Aug 2020 15:54:36 |
| User entered 'None (1)' | System | 15 Aug 2020 15:54:36 |

US3552035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:49:48

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-15T10:54:32', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'd79db794-cac9-44ff-8ff5-ef28a097b2bc' | System | 15 Aug 2020 15:54:36 |
| User entered '15 Aug 2020 10:54' | System | 15 Aug 2020 15:54:36 |

US3552035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:49:48

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| User entered '14 Aug 2020 16:08' | System | 14 Aug 2020 17:26:31 |

US3552035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:49:48

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| User entered '15 Aug 2020 11:59' | System | 14 Aug 2020 17:26:31 |

US3552035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:49:48

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| Data entry locked. | System | 14 Aug 2020 17:26:31 |
| User entered 'Day 2' | System | 14 Aug 2020 17:26:31 |

US3552035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:49:48

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-16T00:23:30', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'c4b65e8b-1eab-4da6-9556-f3c4e987d2a6' | System | 16 Aug 2020 05:25:07 |
| User entered 'Does not interfere with activity (2)' | System | 16 Aug 2020 05:25:07 |

US3552035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:49:48

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-16T00:23:33', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'c4b65e8b-1eab-4da6-9556-f3c4e987d2a6' User entered 'No (N)' | System | 16 Aug 2020 05:25:07 |
| | System | 16 Aug 2020 05:25:07 |

US3552035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:49:48

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-16T00:23:38', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'c4b65e8b-1eab-4da6-9556-f3c4e987d2a6' User entered 'No (N)' | System | 16 Aug 2020 05:25:07 |
| | System | 16 Aug 2020 05:25:07 |

US3552035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:49:48

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-16T00:25:02', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'c4b65e8b-1eab-4da6-9556-f3c4e987d2a6' User entered 'None (1)' | System | 16 Aug 2020 05:25:07 |
| | System | 16 Aug 2020 05:25:07 |

US3552035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:49:48

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-16T00:25:05', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'c4b65e8b-1eab-4da6-9556-f3c4e987d2a6' User entered '16 Aug 2020 00:25' | System | 16 Aug 2020 05:25:07 |
| | System | 16 Aug 2020 05:25:07 |

US3552035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:49:48

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| User entered '15 Aug 2020 12:00' | System | 14 Aug 2020 17:26:31 |

US3552035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:49:48

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| User entered '16 Aug 2020 11:59' | System | 14 Aug 2020 17:26:31 |

US3552035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:49:48

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| Data entry locked. | System | 14 Aug 2020 17:26:31 |
| User entered 'Day 3' | System | 14 Aug 2020 17:26:31 |

US3552035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:49:48

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-16T22:43:13', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '8b6b1fa9-b293-40df-a865-75fb5d6a4aaa' | System | 17 Aug 2020 03:43:37 |
| User entered 'Does not interfere with activity (2)' | System | 17 Aug 2020 03:43:37 |

US3552035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:49:48

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-16T22:43:16', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '8b6b1fa9-b293-40df-a865-75fb5d6a4aaa' | System | 17 Aug 2020 03:43:37 |
| User entered 'No (N)' | System | 17 Aug 2020 03:43:37 |

US3552035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:49:48

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-16T22:43:19', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '8b6b1fa9-b293-40df-a865-75fb5d6a4aaa' | System | 17 Aug 2020 03:43:37 |
| User entered 'No (N)' | System | 17 Aug 2020 03:43:37 |

US3552035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:49:48

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-16T22:43:31', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '8b6b1fa9-b293-40df-a865-75fb5d6a4aaa' | System | 17 Aug 2020 03:43:37 |
| User entered 'None (1)' | System | 17 Aug 2020 03:43:37 |

US3552035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:49:48

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-16T22:43:34', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '8b6b1fa9-b293-40df-a865-75fb5d6a4aaa' User entered '16 Aug 2020 22:43' | System | 17 Aug 2020 03:43:37 |
| | System | 17 Aug 2020 03:43:37 |

US3552035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:49:48

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| User entered '16 Aug 2020 12:00' | System | 14 Aug 2020 17:26:31 |

US3552035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:49:48

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| User entered '17 Aug 2020 11:59' | System | 14 Aug 2020 17:26:31 |

US3552035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:49:48

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| Data entry locked. | System | 14 Aug 2020 17:26:31 |
| User entered 'Day 4' | System | 14 Aug 2020 17:26:31 |

US3552035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:49:48

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-18T02:13:00', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'f3b655ed-883a-481b-9f37-4af45581fd4f' User entered 'None (1)' | System | 18 Aug 2020 07:13:16 |
| | System | 18 Aug 2020 07:13:16 |

US3552035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:49:48

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-18T02:13:04', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'f3b655ed-883a-481b-9f37-4af45581fd4f' User entered 'No (N)' | System | 18 Aug 2020 07:13:16 |
| | System | 18 Aug 2020 07:13:16 |

US3552035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:49:48

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-18T02:13:07', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'f3b655ed-883a-481b-9f37-4af45581fd4f' User entered 'No (N)' | System | 18 Aug 2020 07:13:16 |
| | System | 18 Aug 2020 07:13:16 |

US3552035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:49:48

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-18T02:13:11', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'f3b655ed-883a-481b-9f37-4af45581fd4f' User entered 'None (1)' | System | 18 Aug 2020 07:13:16 |
| | System | 18 Aug 2020 07:13:16 |

US3552035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:49:48

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-18T02:13:14', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'f3b655ed-883a-481b-9f37-4af45581fd4f' User entered '18 Aug 2020 02:13' | System | 18 Aug 2020 07:13:16 |
| | System | 18 Aug 2020 07:13:16 |

US3552035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:49:48

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| User entered '17 Aug 2020 12:00' | System | 14 Aug 2020 17:26:31 |

US3552035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:49:48

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| User entered '18 Aug 2020 11:59' | System | 14 Aug 2020 17:26:31 |

US3552035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:49:48

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| Data entry locked. | System | 14 Aug 2020 17:26:31 |
| User entered 'Day 5' | System | 14 Aug 2020 17:26:31 |

US3552035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:49:48

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-19T00:56:00', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'ca6be480-45c0-4735-b66d-6699e8079ecc' | System | 19 Aug 2020 05:56:14 |
| User entered 'None (1)' | System | 19 Aug 2020 05:56:14 |

US3552035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:49:48

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-19T00:56:03', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'ca6be480-45c0-4735-b66d-6699e8079ecc' User entered 'No (N)' | System | 19 Aug 2020 05:56:14 |
| | System | 19 Aug 2020 05:56:14 |

US3552035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:49:48

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-19T00:56:06', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'ca6be480-45c0-4735-b66d-6699e8079ecc' User entered 'No (N)' | System | 19 Aug 2020 05:56:14 |
| | System | 19 Aug 2020 05:56:14 |

US3552035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:49:48

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-19T00:56:08', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'ca6be480-45c0-4735-b66d-6699e8079ecc' | System | 19 Aug 2020 05:56:14 |
| User entered 'None (1)' | System | 19 Aug 2020 05:56:14 |

US3552035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:49:48

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-19T00:56:10', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'ca6be480-45c0-4735-b66d-6699e8079ecc' User entered '19 Aug 2020 00:56' | System | 19 Aug 2020 05:56:14 |
| | System | 19 Aug 2020 05:56:14 |

US3552035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:49:48

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| User entered '18 Aug 2020 12:00' | System | 14 Aug 2020 17:26:31 |

US3552035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:49:48

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| User entered '19 Aug 2020 11:59' | System | 14 Aug 2020 17:26:31 |

US3552035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:49:48

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| Data entry locked. | System | 14 Aug 2020 17:26:31 |
| User entered 'Day 6' | System | 14 Aug 2020 17:26:31 |

US3552035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:49:48

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-20T02:35:16', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'feb9da16-e431-4f0f-a57a-92401547da56' | System | 20 Aug 2020 07:35:28 |
| User entered 'None (1)' | System | 20 Aug 2020 07:35:28 |

US3552035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:49:48

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-20T02:35:18', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'feb9da16-e431-4f0f-a57a-92401547da56' | System | 20 Aug 2020 07:35:28 |
| User entered 'No (N)' | System | 20 Aug 2020 07:35:28 |

US3552035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:49:48

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-20T02:35:20', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'feb9da16-e431-4f0f-a57a-92401547da56' | System | 20 Aug 2020 07:35:28 |
| User entered 'No (N)' | System | 20 Aug 2020 07:35:28 |

US3552035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:49:48

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-20T02:35:22', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'feb9da16-e431-4f0f-a57a-92401547da56' | System | 20 Aug 2020 07:35:28 |
| User entered 'None (1)' | System | 20 Aug 2020 07:35:28 |

US3552035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:49:48

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-20T02:35:25', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'feb9da16-e431-4f0f-a57a-92401547da56' User entered '20 Aug 2020 02:35' | System | 20 Aug 2020 07:35:28 |
| | System | 20 Aug 2020 07:35:28 |

US3552035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:49:48

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| User entered '19 Aug 2020 12:00' | System | 14 Aug 2020 17:26:31 |

US3552035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:49:48

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| User entered '20 Aug 2020 11:59' | System | 14 Aug 2020 17:26:31 |

US3552035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:49:48

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| Data entry locked. | System | 14 Aug 2020 17:26:31 |
| User entered 'Day 7' | System | 14 Aug 2020 17:26:31 |

US3552035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:49:48

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-20T23:38:38', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'f4a32446-47e2-4974-bcdc-f843e150288c' User entered 'None (1)' | System | 21 Aug 2020 04:38:52 |
| | System | 21 Aug 2020 04:38:52 |

US3552035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:49:48

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-20T23:38:41', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'f4a32446-47e2-4974-bcdc-f843e150288c' User entered 'No (N)' | System | 21 Aug 2020 04:38:52 |
| | System | 21 Aug 2020 04:38:52 |

US3552035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:49:48

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-20T23:38:44', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'f4a32446-47e2-4974-bcdc-f843e150288c' User entered 'No (N)' | System | 21 Aug 2020 04:38:52 |
| | System | 21 Aug 2020 04:38:52 |

US3552035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:49:48

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-20T23:38:46', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'f4a32446-47e2-4974-bcdc-f843e150288c' User entered 'None (1)' | System | 21 Aug 2020 04:38:52 |
| | System | 21 Aug 2020 04:38:52 |

US3552035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:49:48

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-20T23:38:48', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'f4a32446-47e2-4974-bcdc-f843e150288c' User entered '20 Aug 2020 23:38' | System | 21 Aug 2020 04:38:52 |
| | System | 21 Aug 2020 04:38:52 |

US3552035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:49:48

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| User entered '20 Aug 2020 12:00' | System | 14 Aug 2020 17:26:31 |

US3552035

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:49:48

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| User entered '21 Aug 2020 11:59' | System | 14 Aug 2020 17:26:31 |

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:49:48

TIMEPOINT

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| Data entry locked. | System | 14 Aug 2020 17:26:31 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 14 Aug 2020 17:26:31 |

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:49:48

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-14T13:06:06', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '0a9a0909-d0fb-44e3-9cff-96c679da0b96' | System | 14 Aug 2020 18:06:47 |
| User entered 'No interference with activity (1)' | System | 14 Aug 2020 18:06:47 |

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:49:48

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-14T13:06:11', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '0a9a0909-d0fb-44e3-9cff-96c679da0b96' User entered 'None (0)' | System | 14 Aug 2020 18:06:47 |
| | System | 14 Aug 2020 18:06:47 |

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:49:48

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-14T13:06:16', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '0a9a0909-d0fb-44e3-9cff-96c679da0b96' User entered 'None (0)' | System | 14 Aug 2020 18:06:47 |
| | System | 14 Aug 2020 18:06:47 |

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:49:48

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-14T13:06:19', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '0a9a0909-d0fb-44e3-9cff-96c679da0b96' User entered 'None (0)' | System | 14 Aug 2020 18:06:47 |
| | System | 14 Aug 2020 18:06:47 |

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:49:48

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-14T13:06:27', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '0a9a0909-d0fb-44e3-9cff-96c679da0b96' User entered 'None (0)' | System | 14 Aug 2020 18:06:47 |
| | System | 14 Aug 2020 18:06:47 |

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:49:48

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-14T13:06:31', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '0a9a0909-d0fb-44e3-9cff-96c679da0b96' User entered 'None (0)' | System | 14 Aug 2020 18:06:47 |
| | System | 14 Aug 2020 18:06:47 |

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:49:48

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-14T13:06:41', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '0a9a0909-d0fb-44e3-9cff-96c679da0b96' | System | 14 Aug 2020 18:06:47 |
| User entered 'No (N)' | System | 14 Aug 2020 18:06:47 |

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:49:48

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-14T13:06:44', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '0a9a0909-d0fb-44e3-9cff-96c679da0b96' User entered '14 Aug 2020 13:06' | System | 14 Aug 2020 18:06:47 |
| | System | 14 Aug 2020 18:06:47 |

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:49:48

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| User entered '14 Aug 2020 12:43' | System | 14 Aug 2020 17:26:31 |

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:49:48

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| User entered '14 Aug 2020 15:13' | System | 14 Aug 2020 17:26:31 |

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:49:48

TIMEPOINT

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| Data entry locked. | System | 14 Aug 2020 17:26:31 |
| User entered 'Day 1, after vaccination (at home)' | System | 14 Aug 2020 17:26:31 |

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:49:48

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-15T10:54:42', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '8d8b431d-37ad-4e3d-9df7-d324816667c6' | System | 15 Aug 2020 15:55:46 |
| User entered 'No interference with activity (1)' | System | 15 Aug 2020 15:55:46 |

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:49:48

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-15T10:54:51', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '8d8b431d-37ad-4e3d-9df7-d324816667c6' User entered 'None (0)' | System | 15 Aug 2020 15:55:46 |
| | System | 15 Aug 2020 15:55:46 |

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:49:48

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-15T10:55:03', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '8d8b431d-37ad-4e3d-9df7-d324816667c6' User entered 'None (0)' | System | 15 Aug 2020 15:55:46 |
| | System | 15 Aug 2020 15:55:46 |

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:49:48

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-15T10:55:25', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '8d8b431d-37ad-4e3d-9df7-d324816667c6' User entered 'None (0)' | System | 15 Aug 2020 15:55:46 |
| | System | 15 Aug 2020 15:55:46 |

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:49:48

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-15T10:55:32', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '8d8b431d-37ad-4e3d-9df7-d324816667c6' User entered 'None (0)' | System | 15 Aug 2020 15:55:46 |
| | System | 15 Aug 2020 15:55:46 |

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:49:48

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-15T10:55:35', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '8d8b431d-37ad-4e3d-9df7-d324816667c6' User entered 'None (0)' | System | 15 Aug 2020 15:55:46 |
| | System | 15 Aug 2020 15:55:46 |

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:49:48

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-15T10:55:41', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '8d8b431d-37ad-4e3d-9df7-d324816667c6' User entered 'No (N)' | System | 15 Aug 2020 15:55:46 |
| | System | 15 Aug 2020 15:55:46 |

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:49:48

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-15T10:55:44', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '8d8b431d-37ad-4e3d-9df7-d324816667c6' User entered '15 Aug 2020 10:55' | System | 15 Aug 2020 15:55:46 |
| | System | 15 Aug 2020 15:55:46 |

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:49:48

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| User entered '14 Aug 2020 16:08' | System | 14 Aug 2020 17:26:31 |

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:49:48

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| User entered '15 Aug 2020 11:59' | System | 14 Aug 2020 17:26:31 |

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:49:48

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| Data entry locked. | System | 14 Aug 2020 17:26:31 |
| User entered 'Day 2' | System | 14 Aug 2020 17:26:31 |

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:49:48

HEADACHE

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-16T00:25:18', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '5ec4978e-ee56-40d0-8173-5e3a5e96aa41' User entered 'No interference with activity (1)' | System | 16 Aug 2020 05:26:04 |
| | System | 16 Aug 2020 05:26:04 |

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:49:48

FATIGUE

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-16T00:25:29', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '5ec4978e-ee56-40d0-8173-5e3a5e96aa41' User entered 'No interference with activity (1)' | System | 16 Aug 2020 05:26:04 |
| | System | 16 Aug 2020 05:26:04 |

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:49:48

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-16T00:25:34', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '5ec4978e-ee56-40d0-8173-5e3a5e96aa41' User entered 'None (0)' | System | 16 Aug 2020 05:26:04 |
| | System | 16 Aug 2020 05:26:04 |

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:49:48

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-16T00:25:50', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '5ec4978e-ee56-40d0-8173-5e3a5e96aa41' User entered 'No interference with activity (1)' | System | 16 Aug 2020 05:26:04 |
| | System | 16 Aug 2020 05:26:04 |

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:49:48

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-16T00:25:53', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '5ec4978e-ee56-40d0-8173-5e3a5e96aa41' User entered 'None (0)' | System | 16 Aug 2020 05:26:04 |
| | System | 16 Aug 2020 05:26:04 |

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:49:48

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-16T00:25:56', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '5ec4978e-ee56-40d0-8173-5e3a5e96aa41' User entered 'None (0)' | System | 16 Aug 2020 05:26:04 |
| | System | 16 Aug 2020 05:26:04 |

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:49:48

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-16T00:26:00', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '5ec4978e-ee56-40d0-8173-5e3a5e96aa41' User entered 'No (N)' | System | 16 Aug 2020 05:26:04 |
| | System | 16 Aug 2020 05:26:04 |

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:49:48

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-16T00:26:03', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '5ec4978e-ee56-40d0-8173-5e3a5e96aa41' User entered '16 Aug 2020 00:26' | System | 16 Aug 2020 05:26:04 |
| | System | 16 Aug 2020 05:26:04 |

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:49:48

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| User entered '15 Aug 2020 12:00' | System | 14 Aug 2020 17:26:31 |

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:49:48

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| User entered '16 Aug 2020 11:59' | System | 14 Aug 2020 17:26:31 |

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:49:48

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| Data entry locked. | System | 14 Aug 2020 17:26:31 |
| User entered 'Day 3' | System | 14 Aug 2020 17:26:31 |

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:49:48

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-16T22:43:38', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '46761bad-7704-4e60-9f9c-d7777d8047d7' User entered 'None (0)' | System | 17 Aug 2020 03:43:59 |
| | System | 17 Aug 2020 03:43:59 |

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:49:48

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-16T22:43:41', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '46761bad-7704-4e60-9f9c-d7777d8047d7' User entered 'None (0)' | System | 17 Aug 2020 03:43:59 |
| | System | 17 Aug 2020 03:43:59 |

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:49:48

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-16T22:43:44', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '46761bad-7704-4e60-9f9c-d7777d8047d7' User entered 'None (0)' | System | 17 Aug 2020 03:43:59 |
| | System | 17 Aug 2020 03:43:59 |

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:49:48

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-16T22:43:46', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '46761bad-7704-4e60-9f9c-d7777d8047d7' User entered 'None (0)' | System | 17 Aug 2020 03:43:59 |
| | System | 17 Aug 2020 03:43:59 |

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:49:48

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-16T22:43:48', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '46761bad-7704-4e60-9f9c-d7777d8047d7' User entered 'None (0)' | System | 17 Aug 2020 03:43:59 |
| | System | 17 Aug 2020 03:43:59 |

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:49:48

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-16T22:43:50', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '46761bad-7704-4e60-9f9c-d7777d8047d7' User entered 'None (0)' | System | 17 Aug 2020 03:43:59 |
| | System | 17 Aug 2020 03:43:59 |

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:49:48

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-16T22:43:53', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '46761bad-7704-4e60-9f9c-d7777d8047d7' User entered 'No (N)' | System | 17 Aug 2020 03:43:59 |
| | System | 17 Aug 2020 03:43:59 |

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:49:48

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-16T22:43:55', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '46761bad-7704-4e60-9f9c-d7777d8047d7' User entered '16 Aug 2020 22:43' | System | 17 Aug 2020 03:43:59 |
| | System | 17 Aug 2020 03:43:59 |

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:49:48

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| User entered '16 Aug 2020 12:00' | System | 14 Aug 2020 17:26:31 |

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:49:48

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| User entered '17 Aug 2020 11:59' | System | 14 Aug 2020 17:26:31 |

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:49:48

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| Data entry locked. | System | 14 Aug 2020 17:26:31 |
| User entered 'Day 4' | System | 14 Aug 2020 17:26:31 |

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:49:48

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-18T02:13:22', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'e4c33fbb-d9b5-49ba-9a70-7061fa12ba98' | System | 18 Aug 2020 07:13:53 |
| User entered 'None (0)' | System | 18 Aug 2020 07:13:53 |

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:49:48

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-18T02:13:25', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'e4c33fbb-d9b5-49ba-9a70-7061fa12ba98' User entered 'None (0)' | System | 18 Aug 2020 07:13:53 |
| | System | 18 Aug 2020 07:13:53 |

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:49:48

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-18T02:13:28', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'e4c33fbb-d9b5-49ba-9a70-7061fa12ba98' User entered 'None (0)' | System | 18 Aug 2020 07:13:53 |
| | System | 18 Aug 2020 07:13:53 |

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:49:48

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-18T02:13:32', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'e4c33fbb-d9b5-49ba-9a70-7061fa12ba98' User entered 'None (0)' | System | 18 Aug 2020 07:13:53 |
| | System | 18 Aug 2020 07:13:53 |

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:49:48

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-18T02:13:34', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'e4c33fbb-d9b5-49ba-9a70-7061fa12ba98' User entered 'None (0)' | System | 18 Aug 2020 07:13:53 |
| | System | 18 Aug 2020 07:13:53 |

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:49:48

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-18T02:13:42', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'e4c33fbb-d9b5-49ba-9a70-7061fa12ba98' User entered 'None (0)' | System | 18 Aug 2020 07:13:53 |
| | System | 18 Aug 2020 07:13:53 |

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:49:48

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-18T02:13:48', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'e4c33fbb-d9b5-49ba-9a70-7061fa12ba98' User entered 'No (N)' | System | 18 Aug 2020 07:13:53 |
| | System | 18 Aug 2020 07:13:53 |

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:49:48

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-18T02:13:51', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'e4c33fbb-d9b5-49ba-9a70-7061fa12ba98' User entered '18 Aug 2020 02:13' | System | 18 Aug 2020 07:13:53 |
| | System | 18 Aug 2020 07:13:53 |

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:49:48

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| User entered '17 Aug 2020 12:00' | System | 14 Aug 2020 17:26:31 |

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:49:48

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| User entered '18 Aug 2020 11:59' | System | 14 Aug 2020 17:26:31 |

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:49:48

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| Data entry locked. | System | 14 Aug 2020 17:26:31 |
| User entered 'Day 5' | System | 14 Aug 2020 17:26:31 |

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:49:48

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-19T00:56:15', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'ce8f3f4d-61d5-4ca8-a4fe-f8885ca3fe15' User entered 'None (0)' | System | 19 Aug 2020 05:56:35 |
| | System | 19 Aug 2020 05:56:35 |

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:49:48

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-19T00:56:17', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'ce8f3f4d-61d5-4ca8-a4fe-f8885ca3fe15' User entered 'None (0)' | System | 19 Aug 2020 05:56:35 |
| | System | 19 Aug 2020 05:56:35 |

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:49:48

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-19T00:56:21', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'ce8f3f4d-61d5-4ca8-a4fe-f8885ca3fe15' User entered 'None (0)' | System | 19 Aug 2020 05:56:35 |
| | System | 19 Aug 2020 05:56:35 |

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:49:48

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-19T00:56:24', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'ce8f3f4d-61d5-4ca8-a4fe-f8885ca3fe15' User entered 'None (0)' | System | 19 Aug 2020 05:56:35 |
| | System | 19 Aug 2020 05:56:35 |

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:49:48

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-19T00:56:26', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'ce8f3f4d-61d5-4ca8-a4fe-f8885ca3fe15' User entered 'None (0)' | System | 19 Aug 2020 05:56:35 |
| | System | 19 Aug 2020 05:56:35 |

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:49:48

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-19T00:56:28', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'ce8f3f4d-61d5-4ca8-a4fe-f8885ca3fe15' | System | 19 Aug 2020 05:56:35 |
| User entered 'None (0)' | System | 19 Aug 2020 05:56:35 |

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:49:48

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-19T00:56:31', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'ce8f3f4d-61d5-4ca8-a4fe-f8885ca3fe15' | System | 19 Aug 2020 05:56:35 |
| User entered 'No (N)' | System | 19 Aug 2020 05:56:35 |

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:49:48

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-19T00:56:33', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'ce8f3f4d-61d5-4ca8-a4fe-f8885ca3fe15' | System | 19 Aug 2020 05:56:35 |
| User entered '19 Aug 2020 00:56' | System | 19 Aug 2020 05:56:35 |

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:49:48

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| User entered '18 Aug 2020 12:00' | System | 14 Aug 2020 17:26:31 |

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:49:48

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| User entered '19 Aug 2020 11:59' | System | 14 Aug 2020 17:26:31 |

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:49:48

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| Data entry locked. | System | 14 Aug 2020 17:26:31 |
| User entered 'Day 6' | System | 14 Aug 2020 17:26:31 |

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:49:48

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-20T02:35:32', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'f56ebfb8-43ee-4ab1-ab54-866e6b4bbe85' User entered 'None (0)' | System | 20 Aug 2020 07:35:46 |
| | System | 20 Aug 2020 07:35:46 |

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:49:48

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-20T02:35:34', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'f56ebfb8-43ee-4ab1-ab54-866e6b4bbe85' User entered 'None (0)' | System | 20 Aug 2020 07:35:46 |
| | System | 20 Aug 2020 07:35:46 |

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:49:48

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-20T02:35:35', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'f56ebfb8-43ee-4ab1-ab54-866e6b4bbe85' User entered 'None (0)' | System | 20 Aug 2020 07:35:46 |
| | System | 20 Aug 2020 07:35:46 |

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:49:48

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-20T02:35:37', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'f56ebfb8-43ee-4ab1-ab54-866e6b4bbe85' User entered 'None (0)' | System | 20 Aug 2020 07:35:46 |
| | System | 20 Aug 2020 07:35:46 |

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:49:48

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-20T02:35:39', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'f56ebfb8-43ee-4ab1-ab54-866e6b4bbe85' User entered 'None (0)' | System | 20 Aug 2020 07:35:46 |
| | System | 20 Aug 2020 07:35:46 |

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:49:48

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-20T02:35:40', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'f56ebfb8-43ee-4ab1-ab54-866e6b4bbe85' User entered 'None (0)' | System | 20 Aug 2020 07:35:46 |
| | System | 20 Aug 2020 07:35:46 |

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:49:48

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-20T02:35:42', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'f56ebfb8-43ee-4ab1-ab54-866e6b4bbe85' User entered 'No (N)' | System | 20 Aug 2020 07:35:46 |
| | System | 20 Aug 2020 07:35:46 |

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:49:48

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-20T02:35:44', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'f56ebfb8-43ee-4ab1-ab54-866e6b4bbe85' User entered '20 Aug 2020 02:35' | System | 20 Aug 2020 07:35:46 |
| | System | 20 Aug 2020 07:35:46 |

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:49:48

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| User entered '19 Aug 2020 12:00' | System | 14 Aug 2020 17:26:31 |

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:49:48

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| User entered '20 Aug 2020 11:59' | System | 14 Aug 2020 17:26:31 |

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:49:48

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| Data entry locked. | System | 14 Aug 2020 17:26:31 |
| User entered 'Day 7' | System | 14 Aug 2020 17:26:31 |

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:49:48

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-20T23:38:52', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'ceacd112-2c29-40cb-8d14-624125e0bf4c' User entered 'None (0)' | System | 21 Aug 2020 04:39:16 |
| | System | 21 Aug 2020 04:39:16 |

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:49:48

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-20T23:38:55', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'ceacd112-2c29-40cb-8d14-624125e0bf4c' User entered 'None (0)' | System | 21 Aug 2020 04:39:16 |
| | System | 21 Aug 2020 04:39:16 |

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:49:48

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-20T23:38:58', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'ceacd112-2c29-40cb-8d14-624125e0bf4c' User entered 'None (0)' | System | 21 Aug 2020 04:39:16 |
| | System | 21 Aug 2020 04:39:16 |

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:49:48

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-20T23:39:02', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'ceacd112-2c29-40cb-8d14-624125e0bf4c' User entered 'None (0)' | System | 21 Aug 2020 04:39:16 |
| | System | 21 Aug 2020 04:39:16 |

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:49:48

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-20T23:39:06', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'ceacd112-2c29-40cb-8d14-624125e0bf4c' User entered 'None (0)' | System | 21 Aug 2020 04:39:16 |
| | System | 21 Aug 2020 04:39:16 |

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:49:48

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-20T23:39:08', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'ceacd112-2c29-40cb-8d14-624125e0bf4c' User entered 'None (0)' | System | 21 Aug 2020 04:39:16 |
| | System | 21 Aug 2020 04:39:16 |

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:49:48

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-20T23:39:11', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'ceacd112-2c29-40cb-8d14-624125e0bf4c' User entered 'No (N)' | System | 21 Aug 2020 04:39:16 |
| | System | 21 Aug 2020 04:39:16 |

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:49:48

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-08-20T23:39:13', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'ceacd112-2c29-40cb-8d14-624125e0bf4c' User entered '20 Aug 2020 23:39' | System | 21 Aug 2020 04:39:16 |
| | System | 21 Aug 2020 04:39:16 |

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:49:48

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| User entered '20 Aug 2020 12:00' | System | 14 Aug 2020 17:26:31 |

US3552035

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:49:48

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| User entered '21 Aug 2020 11:59' | System | 14 Aug 2020 17:26:31 |

US3552035

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:48

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Sep 2020 17:01:36 |
| User entered 'Yes (Y)' | Mikayla Frye (b) (4) (b) (4) | 21 Aug 2020 20:35:53 |

US3552035

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:48

Date of Contact or Contact Attempt (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Sep 2020 17:01:36 |
| User entered '21 Aug 2020' | Mikayla Frye (b) (4) (b) (4) | 21 Aug 2020 20:35:53 |

US3552035

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:48

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Sep 2020 17:01:36 |
| User entered 'Contact Made (CONTACT MADE)' | Mikayla Frye (b) (4) (b) (4) | 21 Aug 2020 20:35:53 |

US3552035

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:48

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Sep 2020 17:01:36 |
| User entered empty. | Mikayla Frye (b) (4) (b) (4) | 21 Aug 2020 20:35:53 |

US3552035

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:49:48

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 03 Sep 2020 17:01:41 |
| User entered 'Yes (Y)' | Mikayla Frye (b) (4) (b) (4) | 29 Aug 2020 15:40:44 |

US3552035

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:49:48

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User entered 'l' | System | 29 Aug 2020 15:40:44 |

US3552035

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:48

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Oct 2020 17:48:53 |
| User entered 'Yes (Y)' | Mikayla Frye (b) (4) (b) (4) | 29 Aug 2020 15:40:52 |

US3552035

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:48

Date of Contact or Contact Attempt (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Oct 2020 17:48:53 |
| User entered '29 Aug 2020' | Mikayla Frye (b) (4) (b) (4) | 29 Aug 2020 15:40:52 |

US3552035

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:48

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Oct 2020 17:48:53 |
| User entered 'Contact Made (CONTACT MADE)' | Mikayla Frye (b) (4) (b) (4) | 29 Aug 2020 15:40:52 |

US3552035

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:48

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Oct 2020 17:48:53 |
| User entered empty. | Mikayla Frye (b) (4) (b) (4) | 29 Aug 2020 15:40:52 |

US3552035

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:49:48

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Oct 2020 17:48:59 |
| User entered 'Yes (Y)' | Mikayla Frye (b) (4) (b) (4) | 04 Sep 2020 21:17:24 |

US3552035

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:49:48

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User entered 'l' | System | 04 Sep 2020 21:17:24 |

US3552035

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:48

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Oct 2020 17:50:20 |
| User entered 'Yes (Y)' | Mikayla Frye (b) (4) (b) (4) | 04 Sep 2020 21:17:31 |

US3552035

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:48

Date of Contact or Contact Attempt (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) | 11 Nov 2020 16:33:21 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 11 Nov 2020 16:33:21 |
| | Stanley Dublin (b) (4) | 09 Nov 2020 19:02:53 |
| | (b) (4) | 09 Nov 2020 19:02:53 |
| User entered '04 Sep 2020' reason for change: Data Entry Error | Stanley Dublin (b) (4) | 09 Nov 2020 19:02:53 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Oct 2020 17:50:20 |
| | | |
| User entered '4 Sep 2020' | Mikayla Frye (b) (4) | 04 Sep 2020 21:17:31 |
| | (b) (4) | |

US3552035

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:48

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Oct 2020 17:50:20 |
| User entered 'Contact Made (CONTACT MADE)' | Mikayla Frye (b) (4) (b) (4) | 04 Sep 2020 21:17:31 |

US3552035

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:48

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 26 Oct 2020 17:50:20 |
| User entered empty. | Mikayla Frye (b) (4) (b) (4) | 04 Sep 2020 21:17:31 |

US3552035

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:49:48

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 11 Nov 2020 16:33:28 |
| User entered 'Yes (Y)' | Stanley Doublin (b) (4) (b) (4) | 22 Sep 2020 18:34:43 |

US3552035

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:49:48

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User entered 'l' | System | 22 Sep 2020 18:34:43 |

US3552035

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:49:48

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:32:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 11 Nov 2020 16:34:22 |
| User entered 'Yes (Y)' | Stanley Doublin (b) (4) (b) (4) | 22 Sep 2020 18:34:53 |

US3552035

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:49:48

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

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:32:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 11 Nov 2020 16:34:22 |
| User entered '17 Sep 2020' | Stanley Doublin (b) (4) (b) (4) | 22 Sep 2020 18:34:53 |

US3552035

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:49:48

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

| Audit | User | Time (GMT) |
|--------------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:32:03 |
| DataPoint Verified. | (b) (4) | 11 Nov 2020 16:34:22 |
| User entered 'Clinic (Clinic)' | (b) (4), (b) (6) | 11 Nov 2020 16:34:22 |
| | Stanley Doublin (b) (4) | 22 Sep 2020 18:34:53 |
| | (b) (4) | |

US3552035

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:49:48

[Folder OID](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User entered 'VISIT2' | System | 22 Sep 2020 18:34:53 |

US3552035

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:48

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User accepted default value 'Pre-Dose (PREDOSE)' | Stanley Doublin (b) (4) (b) (4) | 22 Sep 2020 18:35:21 |

US3552035

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:48

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:32:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 15:13:54 |
| User entered 'Yes (Y)' | Stanley Doublin (b) (4) (b) (4) | 22 Sep 2020 18:35:21 |

US3552035

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:48

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:32:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 15:13:54 |
| User entered '17 Sep 2020' | Stanley Doublin (b) (4) (b) (4) | 22 Sep 2020 18:35:21 |

US3552035

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:48

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

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:32:03 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 23 Nov 2020 15:13:54 |
| User entered '12:45' | Stanley Doublin (b) (4) | 22 Sep 2020 18:35:21 |
| | (b) (4) | |

US3552035

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:48

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User entered '17 Sep 2020 12:45' | System | 22 Sep 2020 18:35:21 |

US3552035

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:48

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:32:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 15:13:54 |
| User entered '97.7' F | Stanley Doublin (b) (4) (b) (4) | 22 Sep 2020 18:35:21 |

US3552035

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:48

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:32:03 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 23 Nov 2020 15:13:54 |
| User entered 'Oral (Oral)' | Stanley Doublin (b) (4) | 22 Sep 2020 18:35:21 |
| | (b) (4) | |

US3552035

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:48

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:32:03 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 23 Nov 2020 15:13:54 |
| User entered empty. | Stanley Dublin (b) (4) | 22 Sep 2020 18:35:21 |
| | (b) (4) | |

US3552035

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:48

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:32:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 15:13:54 |
| User entered '66' | Stanley Doublin (b) (4) (b) (4) | 22 Sep 2020 18:35:21 |

US3552035

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:48

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User entered 'bpm' | System | 22 Sep 2020 18:35:21 |

US3552035

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:48

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:32:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 15:13:54 |
| User entered '16' | Stanley Doublin (b) (4) (b) (4) | 22 Sep 2020 18:35:21 |

US3552035

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:48

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User entered 'breaths/min' | System | 22 Sep 2020 18:35:21 |

US3552035

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:48

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:32:03 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 23 Nov 2020 15:13:54 |
| User entered '120' | Stanley Doublin (b) (4) | 22 Sep 2020 18:35:21 |
| | (b) (4) | |

US3552035

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:48

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User entered 'mmHg' | System | 22 Sep 2020 18:35:21 |

US3552035

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:48

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:32:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 15:13:54 |
| User entered '74' | Stanley Dublin (b) (4) (b) (4) | 22 Sep 2020 18:35:21 |

US3552035

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:48

Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User entered 'mmHg' | System | 22 Sep 2020 18:35:21 |

US3552035

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:48

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User accepted default value 'Post-Dose (POSTDOSE)' | Stanley Doublin (b) (4) (b) (4) | 22 Sep 2020 18:35:28 |

US3552035

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:48

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:32:03 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 23 Nov 2020 15:13:54 |
| User entered 'No (N)' | Stanley Doublin (b) (4) | 22 Sep 2020 18:35:28 |
| | (b) (4) | |

US3552035

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:48

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:32:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 15:13:54 |
| User entered empty. | Stanley Doublin (b) (4) (b) (4) | 22 Sep 2020 18:35:28 |

US3552035

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:48

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

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:32:03 |
| DataPoint Verified. | (b) (4) | 23 Nov 2020 15:13:54 |
| User entered empty. | (b) (4), (b) (6) | 23 Nov 2020 15:13:54 |
| | Stanley Doublin (b) (4) | 22 Sep 2020 18:35:28 |
| | (b) (4) | |

US3552035

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:48

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User entered empty. | System | 22 Sep 2020 18:35:28 |

US3552035

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:48

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:32:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 15:13:54 |
| User entered empty. | Stanley Dublin (b) (4) (b) (4) | 22 Sep 2020 18:35:28 |

US3552035

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:48

[Route of measurement](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:32:03 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 23 Nov 2020 15:13:54 |
| User entered empty. | Stanley Doublin (b) (4) | 22 Sep 2020 18:35:28 |
| | (b) (4) | |

US3552035

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:48

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:32:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 15:13:54 |
| User entered empty. | Stanley Dublin (b) (4) (b) (4) | 22 Sep 2020 18:35:28 |

US3552035

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:48

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:32:03 |
| DataPoint Verified. | (b) (4) | 23 Nov 2020 15:13:54 |
| User entered empty. | (b) (4), (b) (6) | 23 Nov 2020 15:13:54 |
| | Stanley Doublin (b) (4) | 22 Sep 2020 18:35:28 |
| | (b) (4) | |

US3552035

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:48

[Pulse units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User entered empty. | System | 22 Sep 2020 18:35:28 |

US3552035

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:48

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:32:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 15:13:54 |
| User entered empty. | Stanley Doublin (b) (4) (b) (4) | 22 Sep 2020 18:35:28 |

US3552035

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:48

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User entered empty. | System | 22 Sep 2020 18:35:28 |

US3552035

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:48

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:32:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 15:13:54 |
| User entered empty. | Stanley Doublin (b) (4) (b) (4) | 22 Sep 2020 18:35:28 |

US3552035

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:48

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User entered empty. | System | 22 Sep 2020 18:35:28 |

US3552035

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:48

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

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:32:03 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 23 Nov 2020 15:13:54 |
| User entered empty. | Stanley Doublin (b) (4) | 22 Sep 2020 18:35:28 |
| | (b) (4) | |

US3552035

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:48

Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User entered empty. | System | 22 Sep 2020 18:35:28 |

US3552035

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:49:48

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:32:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 15:14:18 |
| User entered 'Yes (Y)' | Stanley Doublin (b) (4) (b) (4) | 22 Sep 2020 18:35:45 |

US3552035

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:49:48

Date of examination (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:32:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 15:14:18 |
| User entered '17 Sep 2020' | Stanley Doublin (b) (4) (b) (4) | 22 Sep 2020 18:35:45 |

US3552035

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:49:48

[Was study treatment given?](#)

| Audit | User | Time (GMT) |
|--|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:32:03 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 23 Nov 2020 15:14:22 |
| User closed query 'Was study treatment given? Is No but any of these is present: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' (Site from System). | System | 22 Sep 2020 18:38:51 |
| Query 'Was study treatment given? Is No but any of these is present: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' answered by data change (Site from System). | System | 22 Sep 2020 18:38:51 |
| User opened query 'Was study treatment given? Is No but any of these is present: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' (Site from System). | System | 22 Sep 2020 18:38:26 |
| User entered 'No (N)' | Stanley Doublin (b) (4) (b) (4) | 22 Sep 2020 18:38:26 |

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Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:49:48

[If No, reason not given](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:32:03 |
| DataPoint Verified. | (b) (4) | 23 Nov 2020 15:14:22 |
| User entered 'Physician withheld dose due to Adverse Event (PHYSICIAN AE)' | Stanley Dublin (b) (4) | 22 Sep 2020 18:38:26 |
| | (b) (4) | |

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Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:49:48

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) | 28 Mar 2021 08:53:51 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:32:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 15:14:22 |
| User closed query 'Please add AE term (Shingles Infection)' (Site from CRA). | | 18 Nov 2020 17:05:32 |
| Query 'Please add AE term (Shingles Infection)' answered with 'done' (Site from CRA). | Cassandra Zehenny (b) (4) (b) (4) | 18 Nov 2020 16:16:12 |
| User entered 'shingles infection' reason for change: Per Query Resolution | Cassandra Zehenny (b) (4) (b) (4) | 18 Nov 2020 16:15:41 |
| User opened query 'Please add AE term (Shingles Infection)' (Site from CRA). | (b) (4), (b) (6) | 18 Nov 2020 02:26:35 |
| User entered empty. | Stanley Dublin (b) (4) (b) (4) | 22 Sep 2020 18:38:26 |

US3552035

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:49:48

[What was the study treatment?](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User entered empty. | System | 22 Sep 2020 18:38:26 |

US3552035

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:49:48

What was the treatment date? (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:32:03 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 23 Nov 2020 15:14:22 |
| User entered empty; reason for change Data Entry Error | Stanley Doublin (b) (4) | 22 Sep 2020 18:38:51 |
| User entered '17 Sep 2020' | (b) (4) | |
| | Stanley Doublin (b) (4) | 22 Sep 2020 18:38:26 |
| | (b) (4) | |

US3552035

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:49:48

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

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:32:03 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 23 Nov 2020 15:14:22 |
| User entered empty. | Stanley Doublin (b) (4) | 22 Sep 2020 18:38:26 |
| | (b) (4) | |

US3552035

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:49:48

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User entered empty. | System | 22 Sep 2020 18:38:26 |

US3552035

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:49:48

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:32:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 15:14:22 |
| User entered empty. | Stanley Doublin (b) (4) (b) (4) | 22 Sep 2020 18:38:26 |

US3552035

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:49:48

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| DataPoint Verified. | | 23 Nov 2020 15:14:22 |
| User entered empty. | | 22 Sep 2020 18:38:26 |

US3552035

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:49:48

What was the route of administration for the study treatment?

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User entered empty. | System | 22 Sep 2020 18:38:26 |

US3552035

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:49:48

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:32:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 15:14:28 |
| User entered 'Yes (Y)' | Stanley Doublin (b) (4) (b) (4) | 22 Sep 2020 18:39:04 |

US3552035

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:49:48

Collection date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:32:03 |
| User closed query 'Per IMMUNO Lab Recon: it appears a sample was collected on 17SEP2020; however, it has not been received by GCL. Please clarify and, if shipped, please provide tracking details.' (Site from DM). | (b) (4), (b) (6) | 27 Nov 2020 06:00:16 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 15:14:28 |
| Query 'Per IMMUNO Lab Recon: it appears a sample was collected on 17SEP2020; however, it has not been received by GCL. Please clarify and, if shipped, please provide tracking details.' answered with 'No open lab queries, please speak with GCL' (Site from DM). | Heather Douds (b) (4) (b) (4) | 08 Oct 2020 15:37:43 |
| User opened query 'Per IMMUNO Lab Recon: it appears a sample was collected on 17SEP2020; however, it has not been received by GCL. Please clarify and, if shipped, please provide tracking details.' (Site from DM). | (b) (4), (b) (6) | 07 Oct 2020 09:24:46 |
| User entered '17 Sep 2020' | Stanley Dublin (b) (4) (b) (4) | 22 Sep 2020 18:39:04 |

US3552035

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:49:48

Collection time (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:32:03 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 23 Nov 2020 15:14:28 |
| User entered '13:11' | Stanley Doublin (b) (4) | 22 Sep 2020 18:39:04 |
| | (b) (4) | |

US3552035

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:49:48

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User entered '17 Sep 2020 13:11' | System | 22 Sep 2020 18:39:04 |

US3552035

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:49:48

Collection date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:32:03 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 23 Nov 2020 15:16:24 |
| User entered '17 Sep 2020' | Stanley Doublin (b) (4) | 22 Sep 2020 18:39:17 |
| | (b) (4) | |

US3552035

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:49:48

[Lab Test](#)

| Audit | User | Time (GMT) |
|--|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)' | Stanley Doublin (b) (4) (b) (4) | 22 Sep 2020 18:39:17 |

US3552035

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:49:48

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:32:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 15:16:24 |
| User entered 'Yes (Y)' | Stanley Doublin (b) (4) (b) (4) | 22 Sep 2020 18:39:17 |

US3552035

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:49:48

Collection time (00:00 - 23:59)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:32:03 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 23 Nov 2020 15:16:24 |
| User entered '13:14' | Stanley Doublin (b) (4) | 22 Sep 2020 18:39:17 |
| | (b) (4) | |

US3552035

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:49:48

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User entered '17 Sep 2020 13:14' | System | 22 Sep 2020 18:39:17 |

US3552035

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:49:48

[Lab Test](#)

| Audit | User | Time (GMT) |
|--|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)' | Stanley Doublin (b) (4) (b) (4) | 22 Sep 2020 18:39:17 |

US3552035

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:49:48

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:32:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 15:16:24 |
| User entered 'No (N)' | Stanley Doublin (b) (4) (b) (4) | 22 Sep 2020 18:39:17 |

US3552035

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:49:48

Collection time (00:00 - 23:59)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:32:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 15:16:24 |
| User entered empty. | Stanley Doublin (b) (4) (b) (4) | 22 Sep 2020 18:39:17 |

US3552035

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:49:48

Collection date and time (derived)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User entered empty. | System | 22 Sep 2020 18:39:17 |

US3552035

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:49:48

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:32:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Nov 2020 21:05:10 |
| User entered 'Yes (Y)' | Stanley Doublin (b) (4) (b) (4) | 24 Sep 2020 17:12:25 |

US3552035

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:49:48

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User entered 'I' | System | 24 Sep 2020 17:12:25 |

US3552035

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:48

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Nov 2020 21:05:18 |
| User entered 'Yes (Y)' | Stanley Doublin (b) (4) (b) (4) | 24 Sep 2020 17:12:37 |

US3552035

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:48

Date of Contact or Contact Attempt (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Nov 2020 21:05:18 |
| User entered '24 Sep 2020' | Stanley Doublin (b) (4) (b) (4) | 24 Sep 2020 17:12:37 |

US3552035

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:48

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Nov 2020 21:05:18 |
| User entered 'Contact Made (CONTACT MADE)' | Stanley Dublin (b) (4) (b) (4) | 24 Sep 2020 17:12:37 |

US3552035

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:48

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Nov 2020 21:05:18 |
| User entered empty. | Stanley Doublin (b) (4) (b) (4) | 24 Sep 2020 17:12:37 |

US3552035

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:49:48

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 13 Nov 2020 21:05:26 |
| User entered 'Yes (Y)' | Stanley Doublin (b) (4) (b) (4) | 01 Oct 2020 16:51:07 |

US3552035

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:49:48

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User entered 'l' | System | 01 Oct 2020 16:51:07 |

US3552035

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:48

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 15:16:46 |
| User entered 'Yes (Y)' | Stanley Doublin (b) (4) (b) (4) | 01 Oct 2020 16:51:15 |

US3552035

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:48

Date of Contact or Contact Attempt (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 15:16:46 |
| User entered '01 Oct 2020' reason for change: Data Entry Error | Stanley Doublin (b) (4) (b) (4) | 09 Nov 2020 19:03:14 |
| User entered '1 Oct 2020' | Stanley Doublin (b) (4) (b) (4) | 01 Oct 2020 16:51:15 |

US3552035

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:48

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 23 Nov 2020 15:16:46 |
| User entered 'Contact Made (CONTACT MADE)' | Stanley Doublin (b) (4) | 01 Oct 2020 16:51:15 |
| | (b) (4) | |

US3552035

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:48

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 15:16:46 |
| User entered empty. | Stanley Dublin (b) (4) (b) (4) | 01 Oct 2020 16:51:15 |

US3552035

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:49:48

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 15:16:51 |
| User entered 'Yes (Y)' | Stanley Doublin (b) (4) (b) (4) | 08 Oct 2020 19:20:45 |

US3552035

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:49:48

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User entered 'l' | System | 08 Oct 2020 19:20:45 |

US3552035

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:48

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 15:16:56 |
| User entered 'Yes (Y)' | Stanley Doublin (b) (4) (b) (4) | 08 Oct 2020 19:20:55 |

US3552035

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:48

Date of Contact or Contact Attempt (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) | 23 Nov 2020 15:16:56 |
| User entered '08 Oct 2020' reason for change: Data Entry Error | Stanley Doublin (b) (4) | 09 Nov 2020 19:03:24 |
| User entered '8 Oct 2020' | (b) (4) | 08 Oct 2020 19:20:55 |
| | Stanley Doublin (b) (4) | |
| | (b) (4) | |

US3552035

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:48

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 15:16:56 |
| User entered 'Contact Made (CONTACT MADE)' | Stanley Dublin (b) (4) (b) (4) | 08 Oct 2020 19:20:55 |

US3552035

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:48

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) | 23 Nov 2020 15:16:56 |
| User entered empty. | (b) (4), (b) (6) | 23 Nov 2020 15:16:56 |
| | Stanley Doublin (b) (4) | 08 Oct 2020 19:20:55 |
| | (b) (4) | |

US3552035

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:49:48

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 15:17:02 |
| User entered 'Yes (Y)' | Stanley Doublin (b) (4) (b) (4) | 12 Oct 2020 18:58:52 |

US3552035

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:49:48

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User entered 'l' | System | 12 Oct 2020 18:58:52 |

US3552035

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:49:48

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:32:03 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 23 Nov 2020 15:17:07 |
| User entered 'Yes (Y)' | Stanley Doublin (b) (4) | 12 Oct 2020 18:59:15 |
| | (b) (4) | |

US3552035

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:49:48

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

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:32:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 15:17:07 |
| User entered '12 Oct 2020' | Stanley Doublin (b) (4) (b) (4) | 12 Oct 2020 18:59:15 |

US3552035

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:49:48

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

| Audit | User | Time (GMT) |
|--------------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:32:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 15:17:07 |
| User entered 'Clinic (Clinic)' | Stanley Doublin (b) (4) (b) (4) | 12 Oct 2020 18:59:15 |

US3552035

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:49:48

[Folder OID](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User entered 'VISIT3' | System | 12 Oct 2020 18:59:15 |

US3552035

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:48

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:32:03 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 23 Nov 2020 15:17:12 |
| User entered 'No (N)' | Stanley Doublin (b) (4) | 12 Oct 2020 18:59:29 |
| | (b) (4) | |

US3552035

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:48

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:32:03 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 23 Nov 2020 15:17:12 |
| User entered empty. | Stanley Doublin (b) (4) | 12 Oct 2020 18:59:29 |
| | (b) (4) | |

US3552035

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:48

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:32:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 15:17:12 |
| User entered empty. | Stanley Doublin (b) (4) (b) (4) | 12 Oct 2020 18:59:29 |

US3552035

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:48

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User entered empty. | System | 12 Oct 2020 18:59:29 |

US3552035

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:48

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:32:03 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 23 Nov 2020 15:17:12 |
| User entered empty. | Stanley Doublin (b) (4) | 12 Oct 2020 18:59:29 |
| | (b) (4) | |

US3552035

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:48

[Route of measurement](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:32:03 |
| DataPoint Verified. | (b) (4) | 23 Nov 2020 15:17:12 |
| User entered empty. | (b) (4), (b) (6) | 23 Nov 2020 15:17:12 |
| | Stanley Doublin (b) (4) | 12 Oct 2020 18:59:29 |
| | (b) (4) | |

US3552035

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:48

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:32:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 15:17:12 |
| User entered empty. | Stanley Doublin (b) (4) (b) (4) | 12 Oct 2020 18:59:29 |

US3552035

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:48

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:32:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 15:17:12 |
| User entered empty. | Stanley Doublin (b) (4) (b) (4) | 12 Oct 2020 18:59:29 |

US3552035

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:48

[Pulse units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User entered empty. | System | 12 Oct 2020 18:59:29 |

US3552035

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:48

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:32:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 15:17:12 |
| User entered empty. | Stanley Doublin (b) (4) (b) (4) | 12 Oct 2020 18:59:29 |

US3552035

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:48

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User entered empty. | System | 12 Oct 2020 18:59:29 |

US3552035

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:48

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:32:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 15:17:12 |
| User entered empty. | Stanley Doublin (b) (4) (b) (4) | 12 Oct 2020 18:59:29 |

US3552035

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:48

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User entered empty. | System | 12 Oct 2020 18:59:29 |

US3552035

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:48

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:32:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 15:17:12 |
| User entered empty. | Stanley Doublin (b) (4) (b) (4) | 12 Oct 2020 18:59:29 |

US3552035

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:48

Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User entered empty. | System | 12 Oct 2020 18:59:29 |

US3552035

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:48

[Height \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |

US3552035

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:48

Weight (derived)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |

US3552035

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:49:48

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:32:03 |
| DataPoint Verified. | (b) (4) | 23 Nov 2020 15:17:18 |
| User entered 'No (N)' | (b) (4), (b) (6) | 23 Nov 2020 15:17:18 |
| | Stanley Doublin (b) (4) | 12 Oct 2020 18:59:34 |
| | (b) (4) | |

US3552035

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:49:48

Date of examination (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:32:03 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 23 Nov 2020 15:17:18 |
| User entered empty. | Stanley Dublin (b) (4) | 12 Oct 2020 18:59:34 |
| | (b) (4) | |

US3552035

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:49:48

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:32:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 15:17:22 |
| User entered 'Yes (Y)' | Stanley Doublin (b) (4) (b) (4) | 12 Oct 2020 18:59:45 |

US3552035

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:49:48

Collection date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:32:03 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 23 Nov 2020 15:17:22 |
| User entered '12 Oct 2020' | Stanley Doublin (b) (4) | 12 Oct 2020 18:59:45 |
| | (b) (4) | |

US3552035

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:49:48

Collection time (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:32:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 15:17:22 |
| User entered '11:00' | Stanley Doublin (b) (4) (b) (4) | 12 Oct 2020 18:59:45 |

US3552035

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:49:48

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User entered '12 Oct 2020 11:00' | System | 12 Oct 2020 18:59:45 |

US3552035

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:49:48

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:32:03 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 15:17:27 |
| User entered 'Yes (Y)' | Stanley Dublin (b) (4) (b) (4) | 12 Nov 2020 20:01:59 |

US3552035

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:49:48

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User entered 'I' | System | 12 Nov 2020 20:01:59 |

US3552035

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| Data entry locked. | System | 14 Aug 2020 17:26:31 |
| User entered 'Day 64' | System | 14 Aug 2020 17:26:31 |

US3552035

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-10-14T00:50:24', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'c525c1af-077e-4cf4-bb6a-c1bb22972264' User entered 'No (N)' | System | 14 Oct 2020 05:50:44 |
| | System | 14 Oct 2020 05:50:44 |

US3552035

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-10-14T00:50:30', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'c525c1af-077e-4cf4-bb6a-c1bb22972264' | System | 14 Oct 2020 05:50:44 |
| User entered 'No (N)' | System | 14 Oct 2020 05:50:44 |

US3552035

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-10-14T00:50:40', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'c525c1af-077e-4cf4-bb6a-c1bb22972264' User entered '14 Oct 2020 00:50:40' | System | 14 Oct 2020 05:50:44 |
| | System | 14 Oct 2020 05:50:44 |

US3552035

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| Data entry locked. | System | 14 Aug 2020 17:26:31 |
| User entered '14 Oct 2020 00:01' | System | 14 Aug 2020 17:26:31 |

US3552035

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| Data entry locked. | System | 14 Aug 2020 17:26:31 |
| User entered '18 Oct 2020 23:59' | System | 14 Aug 2020 17:26:31 |

US3552035

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| Data entry locked. | System | 14 Aug 2020 17:26:31 |
| User entered 'Day 71' | System | 14 Aug 2020 17:26:31 |

US3552035

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-10-22T14:50:40', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'd6031b18-cf26-40c5-8e3c-be7c32160e6b' User entered 'No (N)' | System | 22 Oct 2020 19:50:56 |
| | System | 22 Oct 2020 19:50:56 |

US3552035

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-10-22T14:50:43', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'd6031b18-cf26-40c5-8e3c-be7c32160e6b' | System | 22 Oct 2020 19:50:56 |
| User entered 'No (N)' | System | 22 Oct 2020 19:50:56 |

US3552035

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-10-22T14:50:50', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'd6031b18-cf26-40c5-8e3c-be7c32160e6b' User entered '22 Oct 2020 14:50:50' | System | 22 Oct 2020 19:50:56 |
| | System | 22 Oct 2020 19:50:56 |

US3552035

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| Data entry locked. | System | 14 Aug 2020 17:26:31 |
| User entered '21 Oct 2020 00:01' | System | 14 Aug 2020 17:26:31 |

US3552035

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| Data entry locked. | System | 14 Aug 2020 17:26:31 |
| User entered '25 Oct 2020 23:59' | System | 14 Aug 2020 17:26:31 |

US3552035

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| Data entry locked. | System | 14 Aug 2020 17:26:31 |
| User entered 'Day 78' | System | 14 Aug 2020 17:26:31 |

US3552035

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-10-28T13:23:49', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'd108cae7-8a97-457c-8882-4cc63034c2f3' | System | 28 Oct 2020 18:24:10 |
| User entered 'No (N)' | System | 28 Oct 2020 18:24:10 |

US3552035

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-10-28T13:23:55', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'd108cae7-8a97-457c-8882-4cc63034c2f3' | System | 28 Oct 2020 18:24:10 |
| User entered 'No (N)' | System | 28 Oct 2020 18:24:10 |

US3552035

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-10-28T13:24:00', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'd108cae7-8a97-457c-8882-4cc63034c2f3' User entered '28 Oct 2020 13:24:00' | System | 28 Oct 2020 18:24:10 |
| | System | 28 Oct 2020 18:24:10 |

US3552035

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| Data entry locked. | System | 14 Aug 2020 17:26:31 |
| User entered '28 Oct 2020 00:01' | System | 14 Aug 2020 17:26:31 |

US3552035

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| Data entry locked. | System | 14 Aug 2020 17:26:31 |
| User entered '01 Nov 2020 23:59' | System | 14 Aug 2020 17:26:31 |

US3552035

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| Data entry locked. | System | 14 Aug 2020 17:26:31 |
| User entered 'Day 92' | System | 14 Aug 2020 17:26:31 |

US3552035

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-11-11T23:49:01', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'af82f553-0426-4762-85f1-765c5c9b872b' User entered 'No (N)' | System | 12 Nov 2020 05:49:11 |
| | System | 12 Nov 2020 05:49:11 |

US3552035

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-11-11T23:49:05', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'af82f553-0426-4762-85f1-765c5c9b872b' | System | 12 Nov 2020 05:49:11 |
| User entered 'No (N)' | System | 12 Nov 2020 05:49:11 |

US3552035

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-11-11T23:49:08', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'af82f553-0426-4762-85f1-765c5c9b872b' User entered '11 Nov 2020 23:49:08' | System | 12 Nov 2020 05:49:11 |
| | System | 12 Nov 2020 05:49:11 |

US3552035

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| Data entry locked. | System | 14 Aug 2020 17:26:31 |
| User entered '11 Nov 2020 00:01' | System | 14 Aug 2020 17:26:31 |

US3552035

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| Data entry locked. | System | 14 Aug 2020 17:26:31 |
| User entered '15 Nov 2020 23:59' | System | 14 Aug 2020 17:26:31 |

US3552035

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| Data entry locked. | System | 14 Aug 2020 17:26:31 |
| User entered 'Day 99' | System | 14 Aug 2020 17:26:31 |

US3552035

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-11-18T00:01:16', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'ab657269-e6a3-4736-acca-8313f37c8dd1' User entered 'No (N)' | System | 18 Nov 2020 06:01:29 |
| | System | 18 Nov 2020 06:01:29 |

US3552035

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-11-18T00:01:21', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'ab657269-e6a3-4736-acca-8313f37c8dd1' | System | 18 Nov 2020 06:01:29 |
| User entered 'No (N)' | System | 18 Nov 2020 06:01:29 |

US3552035

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-11-18T00:01:24', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'ab657269-e6a3-4736-acca-8313f37c8dd1' User entered '18 Nov 2020 00:01:24' | System | 18 Nov 2020 06:01:29 |
| | System | 18 Nov 2020 06:01:29 |

US3552035

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| Data entry locked. | System | 14 Aug 2020 17:26:31 |
| User entered '18 Nov 2020 00:01' | System | 14 Aug 2020 17:26:31 |

US3552035

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Feb 2021 09:52:47 |
| Data entry locked. | System | 14 Aug 2020 17:26:31 |
| User entered '22 Nov 2020 23:59' | System | 14 Aug 2020 17:26:31 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered 'Day 103' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[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 (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-11-23T02:02:25', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '4bd85ffd-928d-4df3-b2df-3fdb4e6f3b3b' User entered 'No (N)' | System | 23 Nov 2020 08:02:43 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

Have you been exposed to someone with 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 (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-11-23T02:02:33', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '4bd85ffd-928d-4df3-b2df-3fdb4e6f3b3b' User entered 'No (N)' | System | 23 Nov 2020 08:02:43 |
| | System | 23 Nov 2020 08:02:43 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-11-23T02:02:36', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '4bd85ffd-928d-4df3-b2df-3fdb4e6f3b3b' User entered '23 Nov 2020 02:02:36' | System | 23 Nov 2020 08:02:43 |
| | System | 23 Nov 2020 08:02:43 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '22 Nov 2020 00:01' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '26 Nov 2020 23:59' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered 'Day 110' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[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 (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-11-29T00:02:35', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '4f0b9c0d-940d-4004-8e19-7edabc22f4d5' | System | 29 Nov 2020 06:02:49 |
| User entered 'No (N)' | System | 29 Nov 2020 06:02:49 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

Have you been exposed to someone with 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 (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-11-29T00:02:41', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '4f0b9c0d-940d-4004-8e19-7edabc22f4d5' User entered 'No (N)' | System | 29 Nov 2020 06:02:49 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-11-29T00:02:45', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '4f0b9c0d-940d-4004-8e19-7edabc22f4d5' User entered '29 Nov 2020 00:02:45' | System | 29 Nov 2020 06:02:49 |
| | System | 29 Nov 2020 06:02:49 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '29 Nov 2020 00:01' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '03 Dec 2020 23:59' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered 'Day 117' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[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 (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-12-10T11:28:28', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'ed50be71-53a5-43d4-8372-2bc0684a3bda' User entered 'No (N)' | System | 10 Dec 2020 17:28:41 |
| | System | 10 Dec 2020 17:28:41 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

Have you been exposed to someone with 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 (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-12-10T11:28:30', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'ed50be71-53a5-43d4-8372-2bc0684a3bda' User entered 'No (N)' | System | 10 Dec 2020 17:28:41 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-12-10T11:28:33', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'ed50be71-53a5-43d4-8372-2bc0684a3bda' User entered '10 Dec 2020 11:28:33' | System | 10 Dec 2020 17:28:41 |
| | System | 10 Dec 2020 17:28:41 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '06 Dec 2020 00:01' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '10 Dec 2020 23:59' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered 'Day 124' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[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 (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-12-13T18:10:52', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '4afdf67f-82c2-4fdb-a658-e196cb9508b5' User entered 'No (N)' | System | 14 Dec 2020 00:11:00 |
| | System | 14 Dec 2020 00:11:00 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

Have you been exposed to someone with 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 (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-12-13T18:10:55', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '4afdf67f-82c2-4fdb-a658-e196cb9508b5' User entered 'No (N)' | System | 14 Dec 2020 00:11:00 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-12-13T18:10:58', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '4afdf67f-82c2-4fdb-a658-e196cb9508b5' User entered '13 Dec 2020 18:10:58' | System | 14 Dec 2020 00:11:00 |
| | System | 14 Dec 2020 00:11:00 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '13 Dec 2020 00:01' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '17 Dec 2020 23:59' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered 'Day 131' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[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 (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-12-20T00:01:13', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '27187bce-86c4-4ea2-88d6-172ac0ed5ad9' User entered 'No (N)' | System | 20 Dec 2020 06:01:24 |
| | System | 20 Dec 2020 06:01:24 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

Have you been exposed to someone with 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 (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-12-20T00:01:16', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '27187bce-86c4-4ea2-88d6-172ac0ed5ad9' User entered 'No (N)' | System | 20 Dec 2020 06:01:24 |
| | System | 20 Dec 2020 06:01:24 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-12-20T00:01:18', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '27187bce-86c4-4ea2-88d6-172ac0ed5ad9' User entered '20 Dec 2020 00:01:18' | System | 20 Dec 2020 06:01:24 |
| | System | 20 Dec 2020 06:01:24 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '20 Dec 2020 00:01' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '24 Dec 2020 23:59' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered 'Day 138' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[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 (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-12-27T02:13:48', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '6e0d3518-0bad-48a6-a6d8-1818b2fde80d' User entered 'No (N)' | System | 27 Dec 2020 08:13:55 |
| | System | 27 Dec 2020 08:13:55 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

Have you been exposed to someone with 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 (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-12-27T02:13:50', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '6e0d3518-0bad-48a6-a6d8-1818b2fde80d' User entered 'No (N)' | System | 27 Dec 2020 08:13:55 |
| | System | 27 Dec 2020 08:13:55 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2020-12-27T02:13:52', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '6e0d3518-0bad-48a6-a6d8-1818b2fde80d' User entered '27 Dec 2020 02:13:52' | System | 27 Dec 2020 08:13:55 |
| | System | 27 Dec 2020 08:13:55 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '27 Dec 2020 00:01' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '31 Dec 2020 23:59' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered 'Day 145' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[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 (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2021-01-03T00:01:26', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '2ec42bce-47ff-416a-b4d9-abcc345c6e01' | System | 03 Jan 2021 06:01:47 |
| User entered 'No (N)' | System | 03 Jan 2021 06:01:47 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

Have you been exposed to someone with 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 (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2021-01-03T00:01:31', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '2ec42bce-47ff-416a-b4d9-abcc345c6e01' User entered 'No (N)' | System | 03 Jan 2021 06:01:47 |
| | System | 03 Jan 2021 06:01:47 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2021-01-03T00:01:33', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '2ec42bce-47ff-416a-b4d9-abcc345c6e01' User entered '03 Jan 2021 00:01:33' | System | 03 Jan 2021 06:01:47 |
| | System | 03 Jan 2021 06:01:47 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '03 Jan 2021 00:01' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '07 Jan 2021 23:59' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered 'Day 152' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[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 (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2021-01-10T11:08:03', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'f13cd23b-ba62-49d4-9a84-3cede02862fc' User entered 'No (N)' | System | 10 Jan 2021 17:09:16 |
| | System | 10 Jan 2021 17:09:16 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

Have you been exposed to someone with 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 (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2021-01-10T11:08:05', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'f13cd23b-ba62-49d4-9a84-3cede02862fc' User entered 'No (N)' | System | 10 Jan 2021 17:09:16 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2021-01-10T11:08:12', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'f13cd23b-ba62-49d4-9a84-3cede02862fc' User entered '10 Jan 2021 11:08:12' | System | 10 Jan 2021 17:09:16 |
| | System | 10 Jan 2021 17:09:16 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '10 Jan 2021 00:01' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '14 Jan 2021 23:59' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered 'Day 159' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[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 (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2021-01-17T00:20:10', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '04d08b47-9501-4b6c-ad43-08e95fb4cc5f' User entered 'No (N)' | System | 17 Jan 2021 06:20:19 |
| | System | 17 Jan 2021 06:20:19 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

Have you been exposed to someone with 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 (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2021-01-17T00:20:12', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '04d08b47-9501-4b6c-ad43-08e95fb4cc5f' User entered 'No (N)' | System | 17 Jan 2021 06:20:19 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2021-01-17T00:20:15', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '04d08b47-9501-4b6c-ad43-08e95fb4cc5f' User entered '17 Jan 2021 00:20:15' | System | 17 Jan 2021 06:20:19 |
| | System | 17 Jan 2021 06:20:19 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '17 Jan 2021 00:01' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '21 Jan 2021 23:59' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered 'Day 166' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[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 (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2021-01-24T00:04:49', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'd3b0bc42-f736-484b-849b-446f42b6b208' User entered 'No (N)' | System | 24 Jan 2021 06:04:59 |
| | System | 24 Jan 2021 06:04:59 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

Have you been exposed to someone with 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 (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2021-01-24T00:04:54', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'd3b0bc42-f736-484b-849b-446f42b6b208' | System | 24 Jan 2021 06:04:59 |
| User entered 'No (N)' | System | 24 Jan 2021 06:04:59 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2021-01-24T00:04:57', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'd3b0bc42-f736-484b-849b-446f42b6b208' User entered '24 Jan 2021 00:04:57' | System | 24 Jan 2021 06:04:59 |
| | System | 24 Jan 2021 06:04:59 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '24 Jan 2021 00:01' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '28 Jan 2021 23:59' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered 'Day 173' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[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 (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2021-02-03T11:43:35', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '2ae91192-317b-4be8-ae11-e9ebae46cbe2' User entered 'No (N)' | System | 03 Feb 2021 17:43:42 |
| | System | 03 Feb 2021 17:43:42 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

Have you been exposed to someone with 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 (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2021-02-03T11:43:37', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '2ae91192-317b-4be8-ae11-e9ebae46cbe2' User entered 'No (N)' | System | 03 Feb 2021 17:43:42 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2021-02-03T11:43:40', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '2ae91192-317b-4be8-ae11-e9ebae46cbe2' User entered '03 Feb 2021 11:43:40' | System | 03 Feb 2021 17:43:42 |
| | System | 03 Feb 2021 17:43:42 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '31 Jan 2021 00:01' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '04 Feb 2021 23:59' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered 'Day 180' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[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 (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2021-02-07T00:41:08', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '4e3341fd-fbac-4e04-8127-ea462274c4f2' User entered 'No (N)' | System | 07 Feb 2021 06:41:19 |
| | System | 07 Feb 2021 06:41:19 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

Have you been exposed to someone with 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 (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2021-02-07T00:41:12', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '4e3341fd-fbac-4e04-8127-ea462274c4f2' User entered 'No (N)' | System | 07 Feb 2021 06:41:19 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2021-02-07T00:41:15', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '4e3341fd-fbac-4e04-8127-ea462274c4f2' User entered '07 Feb 2021 00:41:15' | System | 07 Feb 2021 06:41:19 |
| | System | 07 Feb 2021 06:41:19 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '07 Feb 2021 00:01' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '11 Feb 2021 23:59' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered 'Day 187' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[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 (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2021-02-17T13:32:57', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '477f915b-f062-4f02-a53f-17d49114fbff' User entered 'No (N)' | System | 17 Feb 2021 19:33:09 |
| | System | 17 Feb 2021 19:33:09 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

Have you been exposed to someone with 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 (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2021-02-17T13:33:00', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '477f915b-f062-4f02-a53f-17d49114fbff' User entered 'No (N)' | System | 17 Feb 2021 19:33:09 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48BC36E5-5612-425D-8C3B-44F6C76C55E0)', Time: '2021-02-17T13:33:04', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '477f915b-f062-4f02-a53f-17d49114fbff' User entered '17 Feb 2021 13:33:04' | System | 17 Feb 2021 19:33:09 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '14 Feb 2021 00:01' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '18 Feb 2021 23:59' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered 'Day 194' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[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 (FA527E8A-E7EB-43E6-A5BD-76718B95DDA1)', Time: '2021-02-25T14:39:25-06:00', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '42c2d387-4061-40ed-adf5-11a5386efa8f' User entered 'No (N)' | System | 25 Feb 2021 20:39:37 |
| | System | 25 Feb 2021 20:39:37 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

Have you been exposed to someone with 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 (FA527E8A-E7EB-43E6-A5BD-76718B95DDA1)', Time: '2021-02-25T14:39:30-06:00', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '42c2d387-4061-40ed-adf5-11a5386efa8f' User entered 'No (N)' | System | 25 Feb 2021 20:39:37 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA527E8A-E7EB-43E6-A5BD-76718B95DDA1)', Time: '2021-02-25T14:39:34-06:00', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '42c2d387-4061-40ed-adf5-11a5386efa8f' User entered '25 Feb 2021 20:39:34' | System | 25 Feb 2021 20:39:37 |
| | System | 25 Feb 2021 20:39:37 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '21 Feb 2021 00:01' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '25 Feb 2021 23:59' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered 'Day 201' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[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 (FA527E8A-E7EB-43E6-A5BD-76718B95DDA1)', Time: '2021-03-02T00:04:25-06:00', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '8c82cfa5-cc2c-4724-96c1-b50f619360d2' | System | 02 Mar 2021 06:04:43 |
| User entered 'No (N)' | System | 02 Mar 2021 06:04:43 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

Have you been exposed to someone with 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 (FA527E8A-E7EB-43E6-A5BD-76718B95DDA1)', Time: '2021-03-02T00:04:34-06:00', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '8c82cfa5-cc2c-4724-96c1-b50f619360d2' | System | 02 Mar 2021 06:04:43 |
| User entered 'No (N)' | System | 02 Mar 2021 06:04:43 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA527E8A-E7EB-43E6-A5BD-76718B95DDA1)', Time: '2021-03-02T00:04:38-06:00', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '8c82cfa5-cc2c-4724-96c1-b50f619360d2' | System | 02 Mar 2021 06:04:43 |
| User entered '02 Mar 2021 00:04:38' | System | 02 Mar 2021 06:04:43 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '28 Feb 2021 00:01' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '04 Mar 2021 23:59' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered 'Day 208' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[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 (FA527E8A-E7EB-43E6-A5BD-76718B95DDA1)', Time: '2021-03-07T09:30:19-06:00', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '373eec7b-a63e-46b2-94cc-028df478638d' User entered 'No (N)' | System | 07 Mar 2021 15:30:31 |
| | System | 07 Mar 2021 15:30:31 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

Have you been exposed to someone with 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 (FA527E8A-E7EB-43E6-A5BD-76718B95DDA1)', Time: '2021-03-07T09:30:24-06:00', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '373eec7b-a63e-46b2-94cc-028df478638d' User entered 'No (N)' | System | 07 Mar 2021 15:30:31 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA527E8A-E7EB-43E6-A5BD-76718B95DDA1)', Time: '2021-03-07T09:30:27-06:00', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '373eec7b-a63e-46b2-94cc-028df478638d' User entered '07 Mar 2021 09:30:27' | System | 07 Mar 2021 15:30:31 |
| | System | 07 Mar 2021 15:30:31 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '07 Mar 2021 00:01' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '11 Mar 2021 23:59' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered 'Day 215' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[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 (FA527E8A-E7EB-43E6-A5BD-76718B95DDA1)', Time: '2021-03-14T00:03:01-06:00', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '75bd8234-fc41-4101-94da-855d98fe1050' | System | 14 Mar 2021 06:03:14 |
| User entered 'No (N)' | System | 14 Mar 2021 06:03:14 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

Have you been exposed to someone with 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 (FA527E8A-E7EB-43E6-A5BD-76718B95DDA1)', Time: '2021-03-14T00:03:07-06:00', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '75bd8234-fc41-4101-94da-855d98fe1050' | System | 14 Mar 2021 06:03:14 |
| User entered 'No (N)' | System | 14 Mar 2021 06:03:14 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA527E8A-E7EB-43E6-A5BD-76718B95DDA1)', Time: '2021-03-14T00:03:10-06:00', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '75bd8234-fc41-4101-94da-855d98fe1050' | System | 14 Mar 2021 06:03:14 |
| User entered '14 Mar 2021 00:03:10' | System | 14 Mar 2021 06:03:14 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '14 Mar 2021 00:01' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '18 Mar 2021 23:59' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered 'Day 222' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[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 (FA527E8A-E7EB-43E6-A5BD-76718B95DDA1)', Time: '2021-03-21T11:42:26-05:00', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '8e65c2b8-e969-47ec-bec7-2c285f2ca1c0' | System | 21 Mar 2021 16:42:39 |
| User entered 'No (N)' | System | 21 Mar 2021 16:42:39 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

Have you been exposed to someone with 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 (FA527E8A-E7EB-43E6-A5BD-76718B95DDA1)', Time: '2021-03-21T11:42:34-05:00', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '8e65c2b8-e969-47ec-bec7-2c285f2ca1c0' | System | 21 Mar 2021 16:42:39 |
| User entered 'No (N)' | System | 21 Mar 2021 16:42:39 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA527E8A-E7EB-43E6-A5BD-76718B95DDA1)', Time: '2021-03-21T11:42:37-05:00', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '8e65c2b8-e969-47ec-bec7-2c285f2ca1c0' User entered '21 Mar 2021 11:42:37' | System | 21 Mar 2021 16:42:39 |
| | System | 21 Mar 2021 16:42:39 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '21 Mar 2021 00:01' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '25 Mar 2021 23:59' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered 'Day 229' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[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 (FA527E8A-E7EB-43E6-A5BD-76718B95DDA1)', Time: '2021-03-28T00:05:17-05:00', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'eccb3582-4b9b-4a39-bb06-0b41f9058831' User entered 'No (N)' | System | 28 Mar 2021 05:05:31 |
| | System | 28 Mar 2021 05:05:31 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

Have you been exposed to someone with 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 (FA527E8A-E7EB-43E6-A5BD-76718B95DDA1)', Time: '2021-03-28T00:05:24-05:00', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'eccb3582-4b9b-4a39-bb06-0b41f9058831' User entered 'No (N)' | System | 28 Mar 2021 05:05:31 |
| | System | 28 Mar 2021 05:05:31 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA527E8A-E7EB-43E6-A5BD-76718B95DDA1)', Time: '2021-03-28T00:05:27-05:00', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'eccb3582-4b9b-4a39-bb06-0b41f9058831' User entered '28 Mar 2021 00:05:27' | System | 28 Mar 2021 05:05:31 |
| | System | 28 Mar 2021 05:05:31 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '28 Mar 2021 00:01' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '01 Apr 2021 23:59' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered 'Day 236' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[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 (FA527E8A-E7EB-43E6-A5BD-76718B95DDA1)', Time: '2021-04-06T12:00:20-05:00', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '64a44605-5bb4-4ead-a82a-5627f4daaab2' | System | 06 Apr 2021 17:00:45 |
| User entered 'No (N)' | System | 06 Apr 2021 17:00:45 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

Have you been exposed to someone with 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 (FA527E8A-E7EB-43E6-A5BD-76718B95DDA1)', Time: '2021-04-06T12:00:23-05:00', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '64a44605-5bb4-4ead-a82a-5627f4daaab2' | System | 06 Apr 2021 17:00:45 |
| User entered 'No (N)' | System | 06 Apr 2021 17:00:45 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA527E8A-E7EB-43E6-A5BD-76718B95DDA1)', Time: '2021-04-06T12:00:25-05:00', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '64a44605-5bb4-4ead-a82a-5627f4daaab2' User entered '06 Apr 2021 12:00:25' | System | 06 Apr 2021 17:00:45 |
| | System | 06 Apr 2021 17:00:45 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '04 Apr 2021 00:01' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '08 Apr 2021 23:59' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered 'Day 243' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[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 (FA527E8A-E7EB-43E6-A5BD-76718B95DDA1)', Time: '2021-04-12T10:52:06-05:00', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '8bc8daf7-3505-4d81-a9c0-c05834794b1f' User entered 'No (N)' | System | 12 Apr 2021 15:52:15 |
| | System | 12 Apr 2021 15:52:15 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

Have you been exposed to someone with 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 (FA527E8A-E7EB-43E6-A5BD-76718B95DDA1)', Time: '2021-04-12T10:52:10-05:00', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '8bc8daf7-3505-4d81-a9c0-c05834794b1f' User entered 'No (N)' | System | 12 Apr 2021 15:52:15 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA527E8A-E7EB-43E6-A5BD-76718B95DDA1)', Time: '2021-04-12T10:52:13-05:00', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '8bc8daf7-3505-4d81-a9c0-c05834794b1f' User entered '12 Apr 2021 10:52:13' | System | 12 Apr 2021 15:52:15 |
| | System | 12 Apr 2021 15:52:15 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '11 Apr 2021 00:01' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '15 Apr 2021 23:59' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered 'Day 250' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[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 (FA527E8A-E7EB-43E6-A5BD-76718B95DDA1)', Time: '2021-04-18T00:02:19-05:00', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'a274aae3-9b73-419e-923e-d7bb15ea4a67' User entered 'No (N)' | System | 18 Apr 2021 05:02:48 |
| | System | 18 Apr 2021 05:02:48 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

Have you been exposed to someone with 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 (FA527E8A-E7EB-43E6-A5BD-76718B95DDA1)', Time: '2021-04-18T00:02:24-05:00', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'a274aae3-9b73-419e-923e-d7bb15ea4a67' | System | 18 Apr 2021 05:02:48 |
| User entered 'No (N)' | System | 18 Apr 2021 05:02:48 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA527E8A-E7EB-43E6-A5BD-76718B95DDA1)', Time: '2021-04-18T00:02:27-05:00', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'a274aae3-9b73-419e-923e-d7bb15ea4a67' User entered '18 Apr 2021 00:02:27' | System | 18 Apr 2021 05:02:48 |
| | System | 18 Apr 2021 05:02:48 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '18 Apr 2021 00:01' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '22 Apr 2021 23:59' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered 'Day 257' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[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 (FA527E8A-E7EB-43E6-A5BD-76718B95DDA1)', Time: '2021-04-25T00:04:44-05:00', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'ae7ee0b9-16eb-49cb-8b79-d66ff315dcd3' User entered 'No (N)' | System | 25 Apr 2021 05:06:20 |
| | System | 25 Apr 2021 05:06:20 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

Have you been exposed to someone with 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 (FA527E8A-E7EB-43E6-A5BD-76718B95DDA1)', Time: '2021-04-25T00:04:47-05:00', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'ae7ee0b9-16eb-49cb-8b79-d66ff315dcd3' User entered 'No (N)' | System | 25 Apr 2021 05:06:20 |
| | System | 25 Apr 2021 05:06:20 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA527E8A-E7EB-43E6-A5BD-76718B95DDA1)', Time: '2021-04-25T00:04:50-05:00', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: 'ae7ee0b9-16eb-49cb-8b79-d66ff315dcd3' User entered '25 Apr 2021 00:04:50' | System | 25 Apr 2021 05:06:20 |
| | System | 25 Apr 2021 05:06:20 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '25 Apr 2021 00:01' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '29 Apr 2021 23:59' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered 'Day 264' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[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 (FA527E8A-E7EB-43E6-A5BD-76718B95DDA1)', Time: '2021-05-02T00:03:20-05:00', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '34627102-fb65-42de-9c5c-b6a3fcb0ac81' | System | 02 May 2021 05:03:27 |
| User entered 'No (N)' | System | 02 May 2021 05:03:27 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

Have you been exposed to someone with 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 (FA527E8A-E7EB-43E6-A5BD-76718B95DDA1)', Time: '2021-05-02T00:03:22-05:00', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '34627102-fb65-42de-9c5c-b6a3fcb0ac81' | System | 02 May 2021 05:03:27 |
| User entered 'No (N)' | System | 02 May 2021 05:03:27 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA527E8A-E7EB-43E6-A5BD-76718B95DDA1)', Time: '2021-05-02T00:03:25-05:00', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '34627102-fb65-42de-9c5c-b6a3fcb0ac81' | System | 02 May 2021 05:03:27 |
| User entered '02 May 2021 00:03:25' | System | 02 May 2021 05:03:27 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '02 May 2021 00:01' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '06 May 2021 23:59' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered 'Day 271' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '09 May 2021 00:01' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '13 May 2021 23:59' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered 'Day 278' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '16 May 2021 00:01' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '20 May 2021 23:59' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered 'Day 285' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '23 May 2021 00:01' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '27 May 2021 23:59' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered 'Day 292' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '30 May 2021 00:01' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '03 Jun 2021 23:59' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered 'Day 299' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '06 Jun 2021 00:01' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '10 Jun 2021 23:59' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered 'Day 306' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '13 Jun 2021 00:01' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '17 Jun 2021 23:59' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered 'Day 313' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '20 Jun 2021 00:01' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '24 Jun 2021 23:59' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered 'Day 320' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '27 Jun 2021 00:01' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '01 Jul 2021 23:59' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered 'Day 327' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '04 Jul 2021 00:01' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '08 Jul 2021 23:59' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered 'Day 334' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '11 Jul 2021 00:01' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '15 Jul 2021 23:59' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered 'Day 341' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '18 Jul 2021 00:01' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '22 Jul 2021 23:59' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered 'Day 348' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '25 Jul 2021 00:01' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '29 Jul 2021 23:59' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered 'Day 355' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '01 Aug 2021 00:01' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '05 Aug 2021 23:59' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered 'Day 362' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '08 Aug 2021 00:01' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '12 Aug 2021 23:59' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered 'Day 369' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '15 Aug 2021 00:01' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '19 Aug 2021 23:59' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered 'Day 376' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '22 Aug 2021 00:01' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '26 Aug 2021 23:59' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered 'Day 383' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '29 Aug 2021 00:01' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '02 Sep 2021 23:59' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered 'Day 390' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '05 Sep 2021 00:01' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '09 Sep 2021 23:59' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered 'Day 397' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '12 Sep 2021 00:01' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '16 Sep 2021 23:59' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered 'Day 404' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '19 Sep 2021 00:01' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '23 Sep 2021 23:59' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered 'Day 411' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '26 Sep 2021 00:01' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '30 Sep 2021 23:59' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered 'Day 418' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '03 Oct 2021 00:01' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '07 Oct 2021 23:59' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered 'Day 425' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '10 Oct 2021 00:01' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '14 Oct 2021 23:59' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered 'Day 432' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '17 Oct 2021 00:01' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '21 Oct 2021 23:59' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered 'Day 439' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '24 Oct 2021 00:01' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '28 Oct 2021 23:59' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered 'Day 446' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '31 Oct 2021 00:01' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '04 Nov 2021 23:59' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered 'Day 453' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '07 Nov 2021 00:01' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '11 Nov 2021 23:59' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered 'Day 460' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '14 Nov 2021 00:01' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '18 Nov 2021 23:59' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered 'Day 467' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '21 Nov 2021 00:01' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '25 Nov 2021 23:59' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered 'Day 474' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '28 Nov 2021 00:01' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '02 Dec 2021 23:59' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered 'Day 481' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '05 Dec 2021 00:01' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '09 Dec 2021 23:59' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered 'Day 488' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '12 Dec 2021 00:01' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '16 Dec 2021 23:59' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered 'Day 495' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '19 Dec 2021 00:01' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '23 Dec 2021 23:59' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered 'Day 502' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '26 Dec 2021 00:01' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '30 Dec 2021 23:59' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered 'Day 509' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '02 Jan 2022 00:01' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '06 Jan 2022 23:59' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered 'Day 516' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '09 Jan 2022 00:01' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '13 Jan 2022 23:59' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered 'Day 523' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '16 Jan 2022 00:01' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '20 Jan 2022 23:59' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered 'Day 530' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '23 Jan 2022 00:01' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '27 Jan 2022 23:59' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered 'Day 537' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '30 Jan 2022 00:01' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '03 Feb 2022 23:59' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered 'Day 544' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '06 Feb 2022 00:01' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '10 Feb 2022 23:59' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered 'Day 551' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '13 Feb 2022 00:01' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '17 Feb 2022 23:59' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered 'Day 558' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '20 Feb 2022 00:01' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '24 Feb 2022 23:59' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered 'Day 565' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '27 Feb 2022 00:01' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '03 Mar 2022 23:59' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered 'Day 572' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '06 Mar 2022 00:01' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '10 Mar 2022 23:59' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered 'Day 579' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '13 Mar 2022 00:01' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '17 Mar 2022 23:59' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered 'Day 586' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '20 Mar 2022 00:01' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '24 Mar 2022 23:59' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered 'Day 593' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '27 Mar 2022 00:01' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '31 Mar 2022 23:59' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered 'Day 600' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '03 Apr 2022 00:01' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '07 Apr 2022 23:59' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered 'Day 607' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '10 Apr 2022 00:01' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '14 Apr 2022 23:59' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered 'Day 614' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '17 Apr 2022 00:01' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '21 Apr 2022 23:59' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered 'Day 621' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '24 Apr 2022 00:01' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '28 Apr 2022 23:59' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered 'Day 628' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '01 May 2022 00:01' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '05 May 2022 23:59' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered 'Day 635' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '08 May 2022 00:01' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '12 May 2022 23:59' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered 'Day 642' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '15 May 2022 00:01' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '19 May 2022 23:59' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered 'Day 649' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '22 May 2022 00:01' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '26 May 2022 23:59' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered 'Day 656' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '29 May 2022 00:01' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '02 Jun 2022 23:59' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered 'Day 663' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '05 Jun 2022 00:01' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '09 Jun 2022 23:59' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered 'Day 670' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '12 Jun 2022 00:01' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '16 Jun 2022 23:59' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered 'Day 677' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '19 Jun 2022 00:01' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '23 Jun 2022 23:59' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered 'Day 684' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '26 Jun 2022 00:01' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '30 Jun 2022 23:59' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered 'Day 691' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '03 Jul 2022 00:01' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '07 Jul 2022 23:59' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered 'Day 698' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '10 Jul 2022 00:01' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '14 Jul 2022 23:59' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered 'Day 705' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '17 Jul 2022 00:01' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '21 Jul 2022 23:59' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered 'Day 712' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '24 Jul 2022 00:01' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '28 Jul 2022 23:59' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered 'Day 719' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '31 Jul 2022 00:01' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '04 Aug 2022 23:59' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered 'Day 726' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '07 Aug 2022 00:01' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '11 Aug 2022 23:59' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered 'Day 733' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '14 Aug 2022 00:01' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '18 Aug 2022 23:59' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered 'Day 740' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '21 Aug 2022 00:01' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '25 Aug 2022 23:59' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered 'Day 747' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '28 Aug 2022 00:01' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '01 Sep 2022 23:59' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered 'Day 754' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '04 Sep 2022 00:01' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '08 Sep 2022 23:59' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered 'Day 761' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '11 Sep 2022 00:01' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '15 Sep 2022 23:59' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered 'Day 768' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '18 Sep 2022 00:01' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '22 Sep 2022 23:59' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered 'Day 775' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '25 Sep 2022 00:01' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '29 Sep 2022 23:59' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered 'Day 782' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '02 Oct 2022 00:01' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '06 Oct 2022 23:59' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered 'Day 789' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '09 Oct 2022 00:01' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '13 Oct 2022 23:59' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered 'Day 796' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '16 Oct 2022 00:01' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:49:48

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 07:35:44 |
| Amendment Manager: User entered '20 Oct 2022 23:59' | System | 19 Nov 2020 07:35:44 |

US3552035

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:49:48

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 11:00:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA527E8A-E7EB-43E6-A5BD-76718B95DDA1)', Time: '2021-03-02T00:04:46-06:00', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '7255e7e7-17d2-4046-8fbc-e46f776bcb46' | System | 02 Mar 2021 06:04:54 |
| User entered 'No (N)' | System | 02 Mar 2021 06:04:54 |

US3552035

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:49:48

[Date & Time of Submission](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 11:00:22 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FA527E8A-E7EB-43E6-A5BD-76718B95DDA1)', Time: '2021-03-02T00:04:50-06:00', User OID: 'PatientReportedOutcome (US3552035)', ODM File OID: '7255e7e7-17d2-4046-8fbc-e46f776bcb46' | System | 02 Mar 2021 06:04:54 |
| User entered '02 Mar 2021 00:04:50' | System | 02 Mar 2021 06:04:54 |

US3552035

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:48

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 15:17:33 |
| User entered 'Yes (Y)' | Stanley Doublin (b) (4) (b) (4) | 12 Nov 2020 20:02:08 |

US3552035

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:48

Date of Contact or Contact Attempt (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 15:17:33 |
| User entered '12 Nov 2020' | Stanley Dublin (b) (4) (b) (4) | 12 Nov 2020 20:02:08 |

US3552035

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:48

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 23 Nov 2020 15:17:33 |
| User entered 'Contact Made (CONTACT MADE)' | Stanley Dublin (b) (4) (b) (4) | 12 Nov 2020 20:02:08 |

US3552035

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:48

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 23 Nov 2020 15:17:33 |
| User entered empty. | Stanley Doublin (b) (4) | 12 Nov 2020 20:02:08 |
| | (b) (4) | |

US3552035

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:49:48

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 17 Feb 2021 15:34:29 |
| User entered 'Yes (Y)' | Stanley Doublin (b) (4) (b) (4) | 15 Dec 2020 13:55:29 |

US3552035

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:49:48

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Mar 2021 08:53:51 |
| User entered 'l' | System | 15 Dec 2020 13:55:29 |

US3552035

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:48

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:26:43 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 17 Feb 2021 15:34:34 |
| User entered 'Yes (Y)' | Stanley Doublin (b) (4) (b) (4) | 15 Dec 2020 13:55:37 |

US3552035

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:48

Date of Contact or Contact Attempt (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:26:43 |
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 17 Feb 2021 15:34:34 |
| User entered '14 Dec 2020' | Stanley Dublin (b) (4) | 15 Dec 2020 13:55:37 |

US3552035

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:48

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:26:43 |
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 17 Feb 2021 15:34:34 |
| User entered 'Contact Made (CONTACT MADE)' | Stanley Doublin (b) (4) | 15 Dec 2020 13:55:37 |

US3552035

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:48

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:26:43 |
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) | 17 Feb 2021 15:34:34 |
| User entered empty. | (b) (4), (b) (6) | 17 Feb 2021 15:34:34 |
| | Stanley Doublin (b) (4) | 15 Dec 2020 13:55:37 |
| | (b) (4) | |

US3552035

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:49:48

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:26:43 |
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 17 Feb 2021 15:35:58 |
| User entered 'Yes (Y)' | Stanley Doublin (b) (4) | 12 Jan 2021 17:32:02 |
| | (b) (4) | |

US3552035

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:49:48

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:26:43 |
| User entered 'l' | System | 12 Jan 2021 17:32:02 |

US3552035

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:48

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:26:43 |
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 17 Feb 2021 15:36:02 |
| User entered 'Yes (Y)' | Stanley Doublin (b) (4) | 12 Jan 2021 17:32:10 |

US3552035

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:48

Date of Contact or Contact Attempt (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:26:43 |
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) | 17 Feb 2021 15:36:02 |
| User entered '12 Jan 2021' | Stanley Dublin (b) (4) | 12 Jan 2021 17:32:10 |
| | (b) (4) | |

US3552035

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:48

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:26:43 |
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) | 17 Feb 2021 15:36:02 |
| User entered 'Contact Made (CONTACT MADE)' | Stanley Doublin (b) (4) | 12 Jan 2021 17:32:10 |
| | (b) (4) | |

US3552035

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:48

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:26:43 |
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 17 Feb 2021 15:36:02 |
| User entered empty. | Stanley Doublin (b) (4) | 12 Jan 2021 17:32:10 |
| | (b) (4) | |

US3552035

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:49:48

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:26:43 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 17 Feb 2021 15:36:06 |
| User entered 'Yes (Y)' | Stanley Doublin (b) (4) (b) (4) | 11 Feb 2021 18:38:56 |

US3552035

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:49:48

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:26:43 |
| User entered 'l' | System | 11 Feb 2021 18:38:56 |

US3552035

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:48

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:26:43 |
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 17 Feb 2021 15:36:10 |
| User entered 'Yes (Y)' | Stanley Doublin (b) (4) | 11 Feb 2021 18:39:07 |

US3552035

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:48

Date of Contact or Contact Attempt (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:26:43 |
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 17 Feb 2021 15:36:10 |
| User entered '11 Feb 2021' | Stanley Doublin (b) (4) | 11 Feb 2021 18:39:07 |
| | (b) (4) | |

US3552035

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:48

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:26:43 |
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 17 Feb 2021 15:36:10 |
| User entered 'Contact Made (CONTACT MADE)' | Stanley Doublin (b) (4) | 11 Feb 2021 18:39:07 |
| | (b) (4) | |

US3552035

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:48

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:26:43 |
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 17 Feb 2021 15:36:10 |
| User entered empty. | Stanley Doublin (b) (4) | 11 Feb 2021 18:39:07 |
| | (b) (4) | |

US3552035

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:49:48

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:26:43 |
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 17 Feb 2021 15:36:14 |
| User entered 'Yes (Y)' | Cassandra Zehenny (b) (4) | 11 Feb 2021 19:36:57 |
| | (b) (4) | |

US3552035

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:49:48

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:26:43 |
| User entered 'l' | System | 11 Feb 2021 19:36:57 |

US3552035

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:49:48

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:26:43 |
| DataPoint Verified. | (b) (4), (b) (6) | 29 Mar 2021 16:56:58 |
| User signature succeeded. | sharon frey (b) (4) | 09 Mar 2021 16:50:14 |
| User entered 'Yes (Y)' | (b) (4) Mikayla Frye (b) (4) (b) (4) | 02 Mar 2021 17:29:02 |

US3552035

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:49:48

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

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:26:43 |
| DataPoint Verified. | (b) (4), (b) (6) | 29 Mar 2021 16:56:58 |
| User signature succeeded. | sharon frey (b) (4) | 09 Mar 2021 16:50:14 |
| User entered '02 Mar 2021' | (b) (4) Mikayla Frye (b) (4) (b) (4) | 02 Mar 2021 17:29:02 |

US3552035

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:49:48

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

| Audit | User | Time (GMT) |
|--------------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:26:43 |
| DataPoint Verified. | (b) (4), (b) (6) | 29 Mar 2021 16:56:58 |
| User signature succeeded. | sharon frey (b) (4) | 09 Mar 2021 16:50:14 |
| User entered 'Clinic (Clinic)' | (b) (4) Mikayla Frye (b) (4) (b) (4) | 02 Mar 2021 17:29:02 |

US3552035

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:49:48

[Folder OID](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:26:43 |
| User entered 'VISIT4' | System | 02 Mar 2021 17:29:02 |

US3552035

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:48

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:26:43 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 30 Mar 2021 16:18:22 |
| User entered 'No (N)' | Cassandra Zehenny (b) (4) (b) (4) | 29 Mar 2021 19:52:53 |

US3552035

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:48

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:26:43 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 30 Mar 2021 16:18:22 |
| User entered empty. | Cassandra Zehenny (b) (4) (b) (4) | 29 Mar 2021 19:52:53 |

US3552035

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:48

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

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:26:43 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 30 Mar 2021 16:18:22 |
| User entered empty. | Cassandra Zehenny (b) (4) (b) (4) | 29 Mar 2021 19:52:53 |

US3552035

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:48

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:26:43 |
| User entered empty. | System | 29 Mar 2021 19:52:53 |

US3552035

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:48

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:26:43 |
| User signature succeeded. | sharon frey (b) (4) | 30 Mar 2021 16:18:22 |
| User entered empty. | (b) (4) Cassandra Zehenny (b) (4) | 29 Mar 2021 19:52:53 |

US3552035

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:48

[Route of measurement](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:26:43 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 30 Mar 2021 16:18:22 |
| User entered empty. | Cassandra Zehenny (b) (4) (b) (4) | 29 Mar 2021 19:52:53 |

US3552035

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:48

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:26:43 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 30 Mar 2021 16:18:22 |
| User entered empty. | Cassandra Zehenny (b) (4) (b) (4) | 29 Mar 2021 19:52:53 |

US3552035

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:48

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:26:43 |
| User signature succeeded. | sharon frey (b) (4) | 30 Mar 2021 16:18:22 |
| User entered empty. | (b) (4) Cassandra Zehenny (b) (4) | 29 Mar 2021 19:52:53 |

US3552035

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:48

[Pulse units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:26:43 |
| User entered empty. | System | 29 Mar 2021 19:52:53 |

US3552035

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:48

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

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:26:43 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 30 Mar 2021 16:18:22 |
| User entered empty. | Cassandra Zehenny (b) (4) (b) (4) | 29 Mar 2021 19:52:53 |

US3552035

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:48

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:26:43 |
| User entered empty. | System | 29 Mar 2021 19:52:53 |

US3552035

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:48

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:26:43 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 30 Mar 2021 16:18:22 |
| User entered empty. | Cassandra Zehenny (b) (4) (b) (4) | 29 Mar 2021 19:52:53 |

US3552035

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:48

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:26:43 |
| User entered empty. | System | 29 Mar 2021 19:52:53 |

US3552035

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:48

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:26:43 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 30 Mar 2021 16:18:22 |
| User entered empty. | Cassandra Zehenny (b) (4) (b) (4) | 29 Mar 2021 19:52:53 |

US3552035

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:48

Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:26:43 |
| User entered empty. | System | 29 Mar 2021 19:52:53 |

US3552035

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:48

Height (derived)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:26:43 |

US3552035

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:48

Weight (derived)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:26:43 |

US3552035

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:49:48

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:26:43 |
| DataPoint Verified. | (b) (4), (b) (6) | 29 Mar 2021 16:57:05 |
| User signature succeeded. | sharon frey (b) (4) | 09 Mar 2021 16:50:13 |
| User entered 'No (N)' reason for change: Data Entry Error | (b) (4) | |
| | Mikayla Frye (b) (4) | 02 Mar 2021 17:29:34 |
| User entered 'Yes (Y)' | (b) (4) | |
| | Mikayla Frye (b) (4) | 02 Mar 2021 17:29:09 |
| | (b) (4) | |

US3552035

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:49:48

Date of examination (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:26:43 |
| DataPoint Verified. | (b) (4), (b) (6) | 29 Mar 2021 16:57:05 |
| User signature succeeded. | sharon frey (b) (4) | 09 Mar 2021 16:50:13 |
| User entered empty; reason for change Data Entry Error | (b) (4) | |
| | Mikayla Frye (b) (4) | 02 Mar 2021 17:29:34 |
| User entered '02 Mar 2021' | (b) (4) | |
| | Mikayla Frye (b) (4) | 02 Mar 2021 17:29:09 |
| | (b) (4) | |

US3552035

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:49:48

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:26:43 |
| DataPoint Verified. | (b) (4), (b) (6) | 29 Mar 2021 16:57:07 |
| User signature succeeded. | sharon frey (b) (4) | 09 Mar 2021 16:50:13 |
| User entered 'Yes (Y)' | (b) (4) Mikayla Frye (b) (4) (b) (4) | 02 Mar 2021 17:29:23 |

US3552035

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:49:48

Collection date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:26:43 |
| DataPoint Verified. | (b) (4), (b) (6) | 29 Mar 2021 16:57:07 |
| User signature succeeded. | sharon frey (b) (4) | 09 Mar 2021 16:50:13 |
| User entered '02 Mar 2021' | (b) (4) Mikayla Frye (b) (4) (b) (4) | 02 Mar 2021 17:29:23 |

US3552035

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:49:48

Collection time (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:26:43 |
| DataPoint Verified. | (b) (4), (b) (6) | 29 Mar 2021 16:57:07 |
| User signature succeeded. | sharon frey (b) (4) | 09 Mar 2021 16:50:13 |
| User entered '10:33' | (b) (4) Mikayla Frye (b) (4) (b) (4) | 02 Mar 2021 17:29:23 |

US3552035

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:49:48

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:26:43 |
| User entered '02 Mar 2021 10:33' | System | 02 Mar 2021 17:29:23 |

US3552035

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:49:48

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:26:43 |
| DataPoint Verified. | (b) (4), (b) (6) | 29 Mar 2021 16:57:10 |
| User signature succeeded. | sharon frey (b) (4) | 09 Mar 2021 16:50:13 |
| User entered 'Yes (Y)' | (b) (4) Mikayla Frye (b) (4) (b) (4) | 02 Mar 2021 17:29:38 |

US3552035

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:49:48

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 10:26:43 |
| User entered 'I' | System | 02 Mar 2021 17:29:38 |

US3552035

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:48

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| User signature succeeded. | sharon frey (b) (4) | 16 Apr 2021 17:58:04 |
| User entered 'Yes (Y)' | (b) (4) Stanley Doublin (b) (4) (b) (4) | 15 Apr 2021 18:43:33 |

US3552035

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:48

Date of Contact or Contact Attempt (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| User signature succeeded. | sharon frey (b) (4) | 16 Apr 2021 17:58:04 |
| User entered '15 Apr 2021' | (b) (4) Stanley Doublin (b) (4) (b) (4) | 15 Apr 2021 18:43:33 |

US3552035

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:48

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|---|----------------------|
| User signature succeeded. | sharon frey (b) (4) | 16 Apr 2021 17:58:04 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4) Stanley Doublin (b) (4) (b) (4) | 15 Apr 2021 18:43:33 |

US3552035

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:48

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| User signature succeeded. | sharon frey (b) (4) | 16 Apr 2021 17:58:04 |
| User entered empty. | (b) (4) Stanley Dublin (b) (4) (b) (4) | 15 Apr 2021 18:43:33 |

US3552035

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:49:48

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| User signature succeeded. | sharon frey (b) (4) | 16 Apr 2021 17:58:04 |
| User entered 'Yes (Y)' | (b) (4) Stanley Doublin (b) (4) (b) (4) | 15 Apr 2021 18:46:14 |

US3552035

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:49:48

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 15 Apr 2021 18:46:14 |

US3552035

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

Form: Visit Date

Generated On: 11 Aug 2021 22:49:48

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:25:36 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 17 Feb 2021 15:36:50 |
| User entered 'Yes (Y)' | Stanley Doublin (b) (4) (b) (4) | 20 Jan 2021 13:45:14 |

US3552035

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

Form: Visit Date

Generated On: 11 Aug 2021 22:49:48

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

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:25:36 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 17 Feb 2021 15:36:50 |
| User entered '19 Jan 2021' | Stanley Doublin (b) (4) (b) (4) | 20 Jan 2021 13:45:14 |

US3552035

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

Form: Visit Date

Generated On: 11 Aug 2021 22:49:48

[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 21:25:36 |
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 17 Feb 2021 15:36:50 |
| User entered 'Clinic (Clinic)' | Stanley Doublin (b) (4) | 20 Jan 2021 13:45:14 |

US3552035

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

Form: Visit Date

Generated On: 11 Aug 2021 22:49:48

[Folder OID](#)

| Audit | User | Time (GMT) |
|------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:25:36 |
| User entered 'UNBLND_DECIDE' | System | 20 Jan 2021 13:45:14 |

US3552035

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

Form: Unblinding

Generated On: 11 Aug 2021 22:49:48

Date of updated informed consent (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:25:36 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 17 Feb 2021 15:36:53 |
| User entered '19 Jan 2021' | Stanley Doublin (b) (4) (b) (4) | 20 Jan 2021 13:46:21 |

US3552035

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

Form: Unblinding

Generated On: 11 Aug 2021 22:49:48

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

| Audit | User | Time (GMT) |
|--|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:25:36 |
| User signature succeeded. | sharon frey (b) (4) | 23 Mar 2021 15:20:10 |
| User entered '0' WR# 5295537 | (b) (4) | 10 Mar 2021 16:55:28 |
| Amendment Manager inserted this DataPoint. | System | 06 Mar 2021 16:48:56 |

US3552035

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

Form: Unblinding

Generated On: 11 Aug 2021 22:49:48

[Was the participant unblinded?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:25:36 |
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 17 Feb 2021 15:36:53 |
| User entered 'Yes (Y)' | Stanley Doublin (b) (4) | 20 Jan 2021 13:46:21 |

US3552035

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

Form: Unblinding

Generated On: 11 Aug 2021 22:49:48

[Under what version of the Protocol was the Participant unblinded?](#)

| Audit | User | Time (GMT) |
|---|---------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:25:36 |
| User signature succeeded. | sharon frey (b) (4) | 23 Mar 2021 15:20:10 |
| User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537 | (b) (4) System | 10 Mar 2021 16:55:28 |
| Amendment Manager inserted this DataPoint. | System | 06 Mar 2021 16:48:56 |

US3552035

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

Form: Unblinding

Generated On: 11 Aug 2021 22:49:48

Date of unblinding (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:25:36 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 17 Feb 2021 15:36:53 |
| User entered '19 Jan 2021' | Stanley Doublin (b) (4) (b) (4) | 20 Jan 2021 13:46:21 |

US3552035

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

Form: Unblinding

Generated On: 11 Aug 2021 22:49:48

[Participant randomization assignment](#)

| Audit | User | Time (GMT) |
|--------------------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:25:36 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 17 Feb 2021 15:36:53 |
| User entered 'mRNA-1273 (mRNA-1273)' | Stanley Doublin (b) (4) (b) (4) | 20 Jan 2021 13:46:21 |

US3552035

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

Form: Unblinding

Generated On: 11 Aug 2021 22:49:48

[Actual Dose 1](#)

| Audit | User | Time (GMT) |
|--------------------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:25:36 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 17 Feb 2021 15:36:53 |
| User entered 'mRNA-1273 (mRNA-1273)' | Stanley Doublin (b) (4) (b) (4) | 20 Jan 2021 13:46:21 |

US3552035

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

Form: Unblinding

Generated On: 11 Aug 2021 22:49:48

[Actual Dose 2](#)

| Audit | User | Time (GMT) |
|--------------------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:25:36 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 17 Feb 2021 15:36:53 |
| User entered 'Not Administered (NA)' | Stanley Doublin (b) (4) (b) (4) | 20 Jan 2021 13:46:21 |

US3552035

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

Form: Unblinding

Generated On: 11 Aug 2021 22:49:48

[Will participant receive mRNA-1273?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:25:36 |
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 17 Feb 2021 15:36:53 |
| User entered 'Yes (Y)' | Stanley Doublin (b) (4) | 20 Jan 2021 13:46:21 |
| | (b) (4) | |

US3552035

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

Form: Unblinding

Generated On: 11 Aug 2021 22:49:48

[Placebo Only Flag](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:25:36 |
| User entered empty. | System | 20 Jan 2021 13:46:21 |

US3552035

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

Form: Unblinding

Generated On: 11 Aug 2021 22:49:48

[Continuing with mRNA-1273](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:25:36 |
| User entered 'I' | System | 20 Jan 2021 13:46:21 |

US3552035

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:49:48

[Height](#)

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:25:36 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 17 Feb 2021 15:37:35 |
| User entered missing code ND - Not Done. | Stanley Dublin (b) (4) (b) (4) | 20 Jan 2021 13:46:54 |

US3552035

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:49:48

[Weight](#)

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:25:36 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 17 Feb 2021 15:37:35 |
| User entered missing code ND - Not Done. | Stanley Dublin (b) (4) (b) (4) | 20 Jan 2021 13:46:54 |

US3552035

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:49:48

BMI (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:25:36 |
| User entered empty. | System | 20 Jan 2021 13:46:54 |
| DataPoint set to visible. | System | 20 Jan 2021 13:46:21 |

US3552035

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:49:48

[Height](#)

| Audit | User | Time (GMT) |
|--|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:25:36 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 17 Feb 2021 15:37:35 |
| User entered missing code ND - Not Done. | Stanley Doublin (b) (4) (b) (4) | 20 Jan 2021 13:46:54 |

US3552035

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:49:48

[Weight](#)

| Audit | User | Time (GMT) |
|--|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:25:36 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 17 Feb 2021 15:37:35 |
| User entered missing code ND - Not Done. | Stanley Doublin (b) (4) (b) (4) | 20 Jan 2021 13:46:54 |

US3552035

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:49:48

BMI (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:25:36 |
| User entered empty. | System | 20 Jan 2021 13:46:54 |
| DataPoint set to visible. | System | 20 Jan 2021 13:46:21 |

US3552035

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:48

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:25:36 |
| User accepted default value 'Pre-Dose (PREDOSE)' | Stanley Doublin (b) (4) (b) (4) | 20 Jan 2021 13:46:54 |

US3552035

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:48

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:25:36 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 17 Feb 2021 15:37:35 |
| User entered 'Yes (Y)' | Stanley Doublin (b) (4) (b) (4) | 20 Jan 2021 13:46:54 |

US3552035

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:48

Date of assessment (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:25:36 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 17 Feb 2021 15:37:35 |
| User entered '19 Jan 2021' | Stanley Doublin (b) (4) (b) (4) | 20 Jan 2021 13:46:54 |

US3552035

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:48

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:25:36 |
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 17 Feb 2021 15:37:35 |
| User entered '14:10' | Stanley Dublin (b) (4) | 20 Jan 2021 13:46:54 |

US3552035

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:48

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:25:36 |
| User entered '19 Jan 2021 14:10' | System | 20 Jan 2021 13:46:54 |

US3552035

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:48

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:25:36 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 17 Feb 2021 15:37:35 |
| User entered '98.3' F | Stanley Dublin (b) (4) (b) (4) | 20 Jan 2021 13:46:54 |

US3552035

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:48

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:25:36 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 17 Feb 2021 15:37:35 |
| User entered 'Oral (Oral)' | Stanley Doublin (b) (4) (b) (4) | 20 Jan 2021 13:46:54 |

US3552035

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:48

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:25:36 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 17 Feb 2021 15:37:35 |
| User entered empty. | Stanley Dublin (b) (4) (b) (4) | 20 Jan 2021 13:46:54 |

US3552035

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:48

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:25:36 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 17 Feb 2021 15:37:35 |
| User entered '68' | Stanley Doublin (b) (4) (b) (4) | 20 Jan 2021 13:46:54 |

US3552035

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:48

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:25:36 |
| User entered 'bpm' | System | 20 Jan 2021 13:46:54 |

US3552035

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:48

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:25:36 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 17 Feb 2021 15:37:35 |
| User entered '14' | Stanley Doublin (b) (4) (b) (4) | 20 Jan 2021 13:46:54 |

US3552035

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:48

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:25:36 |
| User entered 'breaths/min' | System | 20 Jan 2021 13:46:54 |

US3552035

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:48

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:25:36 |
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 17 Feb 2021 15:37:35 |
| User entered '123' | Stanley Doublin (b) (4) | 20 Jan 2021 13:46:54 |

US3552035

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:48

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:25:36 |
| User entered 'mmHg' | System | 20 Jan 2021 13:46:54 |

US3552035

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:48

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

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:25:36 |
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) | 17 Feb 2021 15:37:35 |
| User entered '74' | (b) (4), (b) (6) | 17 Feb 2021 15:37:35 |
| | Stanley Doublin (b) (4) | 20 Jan 2021 13:46:54 |
| | (b) (4) | |

US3552035

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:49:48

[Diastolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:25:36 |
| User entered 'mmHg' | System | 20 Jan 2021 13:46:54 |

US3552035

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:49:48

[Height](#)

| Audit | User | Time (GMT) |
|--|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:25:36 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 17 Feb 2021 15:37:35 |
| User entered missing code ND - Not Done. | Stanley Doublin (b) (4) (b) (4) | 20 Jan 2021 13:46:54 |

US3552035

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:49:48

[Weight](#)

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:25:36 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 17 Feb 2021 15:37:35 |
| User entered missing code ND - Not Done. | Stanley Dublin (b) (4) (b) (4) | 20 Jan 2021 13:46:54 |

US3552035

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:49:48

BMI (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:25:36 |
| User entered empty. | System | 20 Jan 2021 13:46:54 |
| DataPoint set to visible. | System | 20 Jan 2021 13:46:21 |

US3552035

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:48

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:25:36 |
| User accepted default value 'Post-Dose (POSTDOSE)' | Stanley Doublin (b) (4) (b) (4) | 20 Jan 2021 13:47:18 |

US3552035

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:48

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:25:36 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 17 Feb 2021 15:37:35 |
| User entered 'Yes (Y)' | Stanley Doublin (b) (4) (b) (4) | 20 Jan 2021 13:47:18 |

US3552035

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:48

Date of assessment (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:25:36 |
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 17 Feb 2021 15:37:35 |
| User entered '19 Jan 2021' | Stanley Doublin (b) (4) | 20 Jan 2021 13:47:18 |

US3552035

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:48

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

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:25:36 |
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 17 Feb 2021 15:37:35 |
| User entered '15:14' | Stanley Doublin (b) (4) | 20 Jan 2021 13:47:18 |

US3552035

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:48

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:25:36 |
| User entered '19 Jan 2021 15:14' | System | 20 Jan 2021 13:47:18 |

US3552035

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:48

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:25:36 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 17 Feb 2021 15:37:35 |
| User entered '98.1' F | Stanley Doublin (b) (4) (b) (4) | 20 Jan 2021 13:47:18 |

US3552035

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:48

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:25:36 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 17 Feb 2021 15:37:35 |
| User entered 'Oral (Oral)' | Stanley Doublin (b) (4) (b) (4) | 20 Jan 2021 13:47:18 |

US3552035

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:48

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:25:36 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 17 Feb 2021 15:37:35 |
| User entered empty. | Stanley Doublin (b) (4) (b) (4) | 20 Jan 2021 13:47:18 |

US3552035

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:48

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:25:36 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 17 Feb 2021 15:37:35 |
| User entered '69' | Stanley Doublin (b) (4) (b) (4) | 20 Jan 2021 13:47:18 |

US3552035

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:48

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:25:36 |
| User entered 'bpm' | System | 20 Jan 2021 13:47:18 |

US3552035

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:48

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:25:36 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 17 Feb 2021 15:37:35 |
| User entered '14' | Stanley Doublin (b) (4) (b) (4) | 20 Jan 2021 13:47:18 |

US3552035

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:48

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:25:36 |
| User entered 'breaths/min' | System | 20 Jan 2021 13:47:18 |

US3552035

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:48

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:25:36 |
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 17 Feb 2021 15:37:35 |
| User entered '132' | Stanley Doublin (b) (4) | 20 Jan 2021 13:47:18 |

US3552035

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:48

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:25:36 |
| User entered 'mmHg' | System | 20 Jan 2021 13:47:18 |

US3552035

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:48

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

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:25:36 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 17 Feb 2021 15:37:35 |
| User entered '86' | Stanley Doublin (b) (4) (b) (4) | 20 Jan 2021 13:47:18 |

US3552035

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:49:48

[Diastolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:25:36 |
| User entered 'mmHg' | System | 20 Jan 2021 13:47:18 |

US3552035

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

Form: Physical Examination

Generated On: 11 Aug 2021 22:49:48

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:25:36 |
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) | 17 Feb 2021 15:37:39 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 17 Feb 2021 15:37:39 |
| | Stanley Doublin (b) (4) | 20 Jan 2021 13:47:38 |
| | (b) (4) | |

US3552035

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

Form: Physical Examination

Generated On: 11 Aug 2021 22:49:48

Date of examination (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:25:36 |
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 17 Feb 2021 15:37:39 |
| User entered '19 Jan 2021' | Stanley Dublin (b) (4) | 20 Jan 2021 13:47:38 |

US3552035

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

Form: Exposure

Generated On: 11 Aug 2021 22:49:48

[Was study treatment given?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:25:36 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 17 Feb 2021 15:37:42 |
| User entered 'Yes (Y)' | Stanley Doublin (b) (4) (b) (4) | 20 Jan 2021 13:48:55 |

US3552035

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

Form: Exposure

Generated On: 11 Aug 2021 22:49:48

[If No, reason not given](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:25:36 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 17 Feb 2021 15:37:42 |
| User entered empty. | Stanley Doublin (b) (4) (b) (4) | 20 Jan 2021 13:48:55 |

US3552035

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

Form: Exposure

Generated On: 11 Aug 2021 22:49:48

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) | 28 Apr 2021 21:25:36 |
| User signature succeeded. | sharon trey (b) (4) (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 17 Feb 2021 15:37:42 |
| User entered empty. | Stanley Doublin (b) (4) (b) (4) | 20 Jan 2021 13:48:55 |

US3552035

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

Form: Exposure

Generated On: 11 Aug 2021 22:49:48

[What was the study treatment? \(Unblinded\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:25:36 |
| User entered 'mRNA-1273' | System | 20 Jan 2021 13:48:55 |
| DataPoint set to visible. | System | 20 Jan 2021 13:46:21 |

US3552035

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

Form: Exposure

Generated On: 11 Aug 2021 22:49:48

[What was the treatment date? \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:25:36 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 17 Feb 2021 15:37:42 |
| User entered '19 Jan 2021' | Stanley Doublin (b) (4) (b) (4) | 20 Jan 2021 13:48:55 |

US3552035

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

Form: Exposure

Generated On: 11 Aug 2021 22:49:48

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

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:25:36 |
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 17 Feb 2021 15:37:42 |
| User entered '14:44' | Stanley Doublin (b) (4) | 20 Jan 2021 13:48:55 |

US3552035

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

Form: Exposure

Generated On: 11 Aug 2021 22:49:48

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:25:36 |
| User entered '19 Jan 2021 14:44' | System | 20 Jan 2021 13:48:55 |

US3552035

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

Form: Exposure

Generated On: 11 Aug 2021 22:49:48

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

| Audit | User | Time (GMT) |
|------------------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:25:36 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 17 Feb 2021 15:37:42 |
| User entered 'Left Arm (LEFT ARM)' | Stanley Doublin (b) (4) (b) (4) | 20 Jan 2021 13:48:55 |

US3552035

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

Form: Exposure

Generated On: 11 Aug 2021 22:49:48

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:25:36 |
| DataPoint Verified. | | 17 Feb 2021 15:37:42 |
| User entered 'ONCE' | System | 20 Jan 2021 13:48:55 |

US3552035

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

Form: Exposure

Generated On: 11 Aug 2021 22:49:48

What was the route of administration for the study treatment?

| Audit | User | Time (GMT) |
|------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:25:36 |
| User entered 'INTRAMUSCULAR' | System | 20 Jan 2021 13:48:55 |

US3552035

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:49:48

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:25:36 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 17 Feb 2021 15:37:48 |
| User entered 'Yes (Y)' | Stanley Doublin (b) (4) (b) (4) | 20 Jan 2021 13:49:12 |

US3552035

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:49:48

Collection date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:25:36 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 17 Feb 2021 15:37:48 |
| User entered '19 Jan 2021' | Stanley Doublin (b) (4) (b) (4) | 20 Jan 2021 13:49:12 |

US3552035

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:49:48

Collection time (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:25:36 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 17 Feb 2021 15:37:48 |
| User entered '14:03' | Stanley Doublin (b) (4) (b) (4) | 20 Jan 2021 13:49:12 |

US3552035

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:49:48

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:25:36 |
| User entered '19 Jan 2021 14:03' | System | 20 Jan 2021 13:49:12 |

US3552035

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:49:48

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:25:36 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 17 Feb 2021 15:37:55 |
| User entered 'Yes (Y)' | Stanley Doublin (b) (4) (b) (4) | 20 Jan 2021 13:49:22 |

US3552035

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:49:48

Collection date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:25:36 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 17 Feb 2021 15:37:55 |
| User entered '19 Jan 2021' | Stanley Doublin (b) (4) (b) (4) | 20 Jan 2021 13:49:22 |

US3552035

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:49:48

[Collection time \(00:00 - 23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:25:36 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 17 Feb 2021 15:37:55 |
| User entered '14:06' | Stanley Doublin (b) (4) (b) (4) | 20 Jan 2021 13:49:22 |

US3552035

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:49:48

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:25:36 |
| User entered '19 Jan 2021 14:06' | System | 20 Jan 2021 13:49:22 |

US3552035

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

Form: Continuing

Generated On: 11 Aug 2021 22:49:48

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:25:36 |
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 17 Feb 2021 15:38:08 |
| User entered 'Yes (Y)' | Stanley Doublin (b) (4) | 26 Jan 2021 18:23:17 |

US3552035

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

Form: Continuing

Generated On: 11 Aug 2021 22:49:48

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:25:36 |
| User entered 'l' | System | 26 Jan 2021 18:23:17 |

US3552035

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:48

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:51:51 |
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 17 Feb 2021 15:38:16 |
| User entered 'Yes (Y)' | Stanley Doublin (b) (4) | 26 Jan 2021 18:23:30 |

US3552035

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:48

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

| Audit | User | Time (GMT) |
|----------------------------|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:51:51 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 17 Feb 2021 15:38:16 |
| User entered '26 Jan 2021' | Stanley Doublin (b) (4) (b) (4) | 26 Jan 2021 18:23:30 |

US3552035

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:48

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:51:51 |
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) | 17 Feb 2021 15:38:16 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4), (b) (6) | 17 Feb 2021 15:38:16 |
| | Stanley Doublin (b) (4) | 26 Jan 2021 18:23:30 |
| | (b) (4) | |

US3552035

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:49:48

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:51:51 |
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) | 17 Feb 2021 15:38:16 |
| User entered empty. | (b) (4), (b) (6) | 17 Feb 2021 15:38:16 |
| | Stanley Doublin (b) (4) | 26 Jan 2021 18:23:30 |
| | (b) (4) | |

US3552035

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:49:48

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:51:51 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 17 Feb 2021 15:38:19 |
| User entered 'Yes (Y)' | Heather Douds (b) (4) (b) (4) | 11 Feb 2021 21:26:29 |

US3552035

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:49:48

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:51:51 |
| User entered 'l' | System | 11 Feb 2021 21:26:29 |

US3552035

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:49:48

[OLD29 Placebo Flag](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 15:51:51 |
| User entered 'I' | System | 11 Feb 2021 21:26:29 |
| DataPoint set to visible. | System | 11 Feb 2021 21:26:29 |

US3552035

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:49:48

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:33:49 |
| DataPoint Verified. | (b) (4), (b) (6) | 29 Mar 2021 16:58:52 |
| User signature succeeded. | sharon frey (b) (4) | 09 Mar 2021 16:50:13 |
| User entered 'Yes (Y)' | (b) (4) Mikayla Frye (b) (4) (b) (4) | 02 Mar 2021 17:29:56 |

US3552035

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:49:48

Visit date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:33:49 |
| DataPoint Verified. | (b) (4), (b) (6) | 29 Mar 2021 16:58:52 |
| User signature succeeded. | sharon frey (b) (4) | 09 Mar 2021 16:50:13 |
| User entered '02 Mar 2021' | (b) (4) Mikayla Frye (b) (4) (b) (4) | 02 Mar 2021 17:29:56 |

US3552035

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:49:48

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

| Audit | User | Time (GMT) |
|--------------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:33:49 |
| DataPoint Verified. | (b) (4), (b) (6) | 29 Mar 2021 16:58:52 |
| User signature succeeded. | sharon frey (b) (4) | 09 Mar 2021 16:50:13 |
| User entered 'Clinic (Clinic)' | (b) (4) Mikayla Frye (b) (4) (b) (4) | 02 Mar 2021 17:29:56 |

US3552035

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:49:48

[Folder OID](#)

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:33:49 |
| User entered 'OLD29' | System | 02 Mar 2021 17:29:56 |

US3552035

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:48

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:33:49 |
| DataPoint Verified. | (b) (4), (b) (6) | 29 Mar 2021 16:58:56 |
| User signature succeeded. | sharon frey (b) (4) | 09 Mar 2021 16:50:13 |
| User entered 'No (N)' | (b) (4) Mikayla Frye (b) (4) (b) (4) | 02 Mar 2021 17:30:16 |

US3552035

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:48

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:33:49 |
| DataPoint Verified. | (b) (4), (b) (6) | 29 Mar 2021 16:58:56 |
| User signature succeeded. | sharon frey (b) (4) | 09 Mar 2021 16:50:13 |
| User entered empty. | (b) (4) Mikayla Frye (b) (4) (b) (4) | 02 Mar 2021 17:30:16 |

US3552035

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:48

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

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:33:49 |
| DataPoint Verified. | (b) (4), (b) (6) | 29 Mar 2021 16:58:56 |
| User signature succeeded. | sharon frey (b) (4) | 09 Mar 2021 16:50:13 |
| User entered empty. | (b) (4) Mikayla Frye (b) (4) (b) (4) | 02 Mar 2021 17:30:16 |

US3552035

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:48

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:33:49 |
| User entered empty. | System | 02 Mar 2021 17:30:16 |

US3552035

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:48

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:33:49 |
| DataPoint Verified. | (b) (4), (b) (6) | 29 Mar 2021 16:58:56 |
| User signature succeeded. | sharon frey (b) (4) | 09 Mar 2021 16:50:13 |
| User entered empty. | (b) (4) Mikayla Frye (b) (4) (b) (4) | 02 Mar 2021 17:30:16 |

US3552035

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:48

[Route of measurement](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:33:49 |
| DataPoint Verified. | (b) (4), (b) (6) | 29 Mar 2021 16:58:56 |
| User signature succeeded. | sharon frey (b) (4) | 09 Mar 2021 16:50:13 |
| User entered empty. | (b) (4) Mikayla Frye (b) (4) (b) (4) | 02 Mar 2021 17:30:16 |

US3552035

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:48

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:33:49 |
| DataPoint Verified. | (b) (4), (b) (6) | 29 Mar 2021 16:58:56 |
| User signature succeeded. | sharon frey (b) (4) | 09 Mar 2021 16:50:13 |
| User entered empty. | (b) (4) Mikayla Frye (b) (4) (b) (4) | 02 Mar 2021 17:30:16 |

US3552035

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:48

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:33:49 |
| DataPoint Verified. | (b) (4), (b) (6) | 29 Mar 2021 16:58:56 |
| User signature succeeded. | sharon frey (b) (4) | 09 Mar 2021 16:50:13 |
| User entered empty. | (b) (4) Mikayla Frye (b) (4) (b) (4) | 02 Mar 2021 17:30:16 |

US3552035

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:48

[Pulse units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:33:49 |
| User entered empty. | System | 02 Mar 2021 17:30:16 |

US3552035

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:48

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

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:33:49 |
| DataPoint Verified. | (b) (4), (b) (6) | 29 Mar 2021 16:58:56 |
| User signature succeeded. | sharon frey (b) (4) | 09 Mar 2021 16:50:13 |
| User entered empty. | (b) (4) Mikayla Frye (b) (4) (b) (4) | 02 Mar 2021 17:30:16 |

US3552035

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:48

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:33:49 |
| User entered empty. | System | 02 Mar 2021 17:30:16 |

US3552035

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:48

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:33:49 |
| DataPoint Verified. | (b) (4), (b) (6) | 29 Mar 2021 16:58:56 |
| User signature succeeded. | sharon frey (b) (4) | 09 Mar 2021 16:50:13 |
| User entered empty. | (b) (4) Mikayla Frye (b) (4) (b) (4) | 02 Mar 2021 17:30:16 |

US3552035

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:48

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:33:49 |
| User entered empty. | System | 02 Mar 2021 17:30:16 |

US3552035

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:48

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:33:49 |
| DataPoint Verified. | (b) (4), (b) (6) | 29 Mar 2021 16:58:56 |
| User signature succeeded. | sharon frey (b) (4) | 09 Mar 2021 16:50:13 |
| User entered empty. | (b) (4) Mikayla Frye (b) (4) (b) (4) | 02 Mar 2021 17:30:16 |

US3552035

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:48

Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:33:49 |
| User entered empty. | System | 02 Mar 2021 17:30:16 |

US3552035

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:48

Height (derived)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:33:49 |

US3552035

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:49:48

Weight (derived)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:33:49 |

US3552035

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:49:48

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:33:49 |
| DataPoint Verified. | (b) (4), (b) (6) | 29 Mar 2021 16:58:46 |
| User signature succeeded. | sharon frey (b) (4) | 09 Mar 2021 16:50:13 |
| User entered 'No (N)' | (b) (4) Mikayla Frye (b) (4) (b) (4) | 02 Mar 2021 17:30:20 |

US3552035

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:49:48

Date of examination (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:33:49 |
| DataPoint Verified. | (b) (4), (b) (6) | 29 Mar 2021 16:58:46 |
| User signature succeeded. | sharon frey (b) (4) | 09 Mar 2021 16:50:13 |
| User entered empty. | (b) (4) Mikayla Frye (b) (4) (b) (4) | 02 Mar 2021 17:30:20 |

US3552035

Folder: OL-D29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:49:48

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:33:49 |
| DataPoint Verified. | (b) (4), (b) (6) | 29 Mar 2021 16:56:47 |
| User signature succeeded. | sharon frey (b) (4) | 09 Mar 2021 16:50:13 |
| User entered 'Yes (Y)' | (b) (4) Mikayla Frye (b) (4) (b) (4) | 02 Mar 2021 17:30:34 |

US3552035

Folder: OL-D29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:49:48

Collection date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:33:49 |
| DataPoint Verified. | (b) (4), (b) (6) | 29 Mar 2021 16:56:47 |
| User signature succeeded. | sharon frey (b) (4) | 09 Mar 2021 16:50:13 |
| User entered '02 Mar 2021' | (b) (4) Mikayla Frye (b) (4) (b) (4) | 02 Mar 2021 17:30:34 |

US3552035

Folder: OL-D29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:49:48

Collection time (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:33:49 |
| DataPoint Verified. | (b) (4), (b) (6) | 29 Mar 2021 16:56:47 |
| User signature succeeded. | sharon frey (b) (4) | 09 Mar 2021 16:50:13 |
| User entered '10:33' | (b) (4) Mikayla Frye (b) (4) (b) (4) | 02 Mar 2021 17:30:34 |

US3552035

Folder: OL-D29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:49:48

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 15:33:49 |
| User entered '02 Mar 2021 10:33' | System | 02 Mar 2021 17:30:34 |

US3552035

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 11 Aug 2021 22:49:48

[Did the participant experience any adverse events?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 15:26:23 |
| Data entry locked. | | 03 May 2021 15:13:25 |
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 09 Nov 2020 04:27:34 |
| User entered 'Yes (Y)' | Mikayla Frye (b) (4) (b) (4) | 04 Sep 2020 21:22:27 |

US3552035

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:49:48

[Adverse event](#)

| Audit | User | Time (GMT) |
|---|---------------------------|----------------------|
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 10 Nov 2020 19:22:48 |
| User closed query 'Per DM CLR: Please specify the location if BILATERAL, LEFT, or RIGHT. Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable. ' (Site from DM). | | 05 Oct 2020 09:04:57 |
| Query 'Per DM CLR: Please specify the location if BILATERAL, LEFT, or RIGHT. Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable. | Cassandra Zehenny (b) (4) | 29 Sep 2020 18:59:48 |
| ' answered with 'data pending' (Site from DM). | | |
| User opened query 'Per DM CLR: Please specify the location if BILATERAL, LEFT, or RIGHT. Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable. ' (Site from DM). | (b) (4), (b) (6) | 29 Sep 2020 05:09:28 |
| User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Herpes viral infections, PT: Herpes zoster, LLT: Shingles - version MedDRA\23.0. | Coder Import (b) (4) | 04 Sep 2020 21:25:46 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0. | Coder Import (b) (4) | 04 Sep 2020 21:25:46 |
| Data point term sent to Coder | System | 04 Sep 2020 21:24:35 |
| User entered 'shingles' | Mikayla Frye (b) (4) | 04 Sep 2020 21:23:55 |
| | (b) (4) | |

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:49:48

[Was this a medically-attended AE?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 10 Nov 2020 19:22:48 |
| User entered 'Yes (Y)' | Mikayla Frye (b) (4) | 04 Sep 2020 21:23:55 |
| | (b) (4) | |

US3552035

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:49:48

[Was this a Solicited Adverse Reaction?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 10 Nov 2020 19:22:48 |
| User entered 'No (N)' | Mikayla Frye (b) (4) (b) (4) | 04 Sep 2020 21:23:55 |

US3552035

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:49:48

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 10 Nov 2020 19:22:48 |
| User entered 'No (N)' | Mikayla Frye (b) (4) (b) (4) | 04 Sep 2020 21:23:55 |

US3552035

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:49:48

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 10 Nov 2020 19:22:48 |
| User entered '04 Sep 2020' reason for change: Data Entry Error | Stanley Dublin (b) (4) | 09 Nov 2020 19:03:55 |
| User entered '4 Sep 2020' | (b) (4) | |
| | Mikayla Frye (b) (4) | 04 Sep 2020 21:23:55 |
| | (b) (4) | |

US3552035

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:49:48

Start time (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 10 Nov 2020 19:22:48 |
| User entered empty. | Mikayla Frye (b) (4) (b) (4) | 04 Sep 2020 21:23:55 |

US3552035

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:49:48

[AE start date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 04 Sep 2020 21:23:55 |

US3552035

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:49:48

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 10 Nov 2020 19:22:48 |
| User entered 'No (N)' reason for change: Data Entry Error | Stanley Dublin (b) (4) | 24 Sep 2020 17:11:59 |
| User entered 'Yes (Y)' | (b) (4) | |
| | Mikayla Frye (b) (4) | 04 Sep 2020 21:23:55 |
| | (b) (4) | |

US3552035

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:49:48

If not Ongoing, end date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 10 Nov 2020 19:22:48 |
| User entered '21 Sep 2020' reason for change: Data Entry Error | Stanley Dublin (b) (4) | 24 Sep 2020 17:11:59 |
| User entered empty. | (b) (4) | |
| | Mikayla Frye (b) (4) | 04 Sep 2020 21:23:55 |
| | (b) (4) | |

US3552035

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:49:48

End time (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 10 Nov 2020 19:22:48 |
| User entered empty. | Mikayla Frye (b) (4) | 04 Sep 2020 21:23:55 |
| | (b) (4) | |

US3552035

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:49:48

[AE End Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 04 Sep 2020 21:23:55 |

US3552035

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:49:48

[Severity](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 10 Nov 2020 19:22:48 |
| User entered 'Grade 1/Mild (Grade 1/Mild)' | Mikayla Frye (b) (4) | 04 Sep 2020 21:23:55 |
| | (b) (4) | |

US3552035

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:49:48

[Is the adverse event serious?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 10 Nov 2020 19:22:48 |
| User entered 'No (N)' | Mikayla Frye (b) (4) | 04 Sep 2020 21:23:55 |
| | (b) (4) | |

US3552035

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:49:48

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 10 Nov 2020 19:22:48 |
| User entered '0' | Mikayla Frye (b) (4) | 04 Sep 2020 21:23:55 |
| | (b) (4) | |

US3552035

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:49:48

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 10 Nov 2020 19:22:48 |
| User entered '0' | Mikayla Frye (b) (4) | 04 Sep 2020 21:23:55 |
| | (b) (4) | |

US3552035

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:49:48

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 10 Nov 2020 19:22:48 |
| User entered '0' | Mikayla Frye (b) (4) (b) (4) | 04 Sep 2020 21:23:55 |

US3552035

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:49:48

Hospital Admission Date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 10 Nov 2020 19:22:48 |
| User entered empty. | Mikayla Frye (b) (4) | 04 Sep 2020 21:23:55 |
| | (b) (4) | |

US3552035

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:49:48

Hospital Discharge Date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 10 Nov 2020 19:22:48 |
| User entered empty. | Mikayla Frye (b) (4) (b) (4) | 04 Sep 2020 21:23:55 |

US3552035

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:49:48

[Admitted to ICU?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 10 Nov 2020 19:22:48 |
| User entered empty. | Mikayla Frye (b) (4) (b) (4) | 04 Sep 2020 21:23:55 |

US3552035

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:49:48

[Number of Days in ICU](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 10 Nov 2020 19:22:48 |
| User entered empty. | Mikayla Frye (b) (4) | 04 Sep 2020 21:23:55 |
| | (b) (4) | |

US3552035

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:49:48

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 10 Nov 2020 19:22:48 |
| User entered '0' | Mikayla Frye (b) (4) | 04 Sep 2020 21:23:55 |
| | (b) (4) | |

US3552035

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:49:48

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 10 Nov 2020 19:22:48 |
| User entered '0' | Mikayla Frye (b) (4) | 04 Sep 2020 21:23:55 |
| | (b) (4) | |

US3552035

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:49:48

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 10 Nov 2020 19:22:48 |
| User entered '0' | Mikayla Frye (b) (4) | 04 Sep 2020 21:23:55 |
| | (b) (4) | |

US3552035

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:49:48

[Relationship to investigational product](#)

| Audit | User | Time (GMT) |
|---|---------------------------------|----------------------|
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 10 Nov 2020 19:22:48 |
| User closed query 'Action taken with investigational product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' (Site from System). | System | 11 Sep 2020 11:58:12 |
| User opened query 'Action taken with investigational product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' (Site from System). | System | 10 Sep 2020 14:31:16 |
| User closed query 'Data is required. Please complete.' (Site from System). | System | 05 Sep 2020 14:30:06 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 05 Sep 2020 14:30:06 |
| User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error | Joan Siegner (b) (4) (b) (4) | 05 Sep 2020 14:30:06 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 04 Sep 2020 21:23:55 |
| User entered empty. | Mikayla Frye (b) (4) (b) (4) | 04 Sep 2020 21:23:55 |

US3552035

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:49:48

[Relationship to Study Procedure](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 10 Nov 2020 19:22:48 |
| User closed query 'Data is required. Please complete.' (Site from System). | System | 05 Sep 2020 14:30:06 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 05 Sep 2020 14:30:06 |
| User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error | Joan Siegner (b) (4) | 05 Sep 2020 14:30:06 |
| | | |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 04 Sep 2020 21:23:55 |
| User entered empty. | Mikayla Frye (b) (4) | 04 Sep 2020 21:23:55 |
| | (b) (4) | |

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:49:48

Action taken with investigational product

| Audit | User | Time (GMT) |
|--|---------------------------|----------------------|
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 19 Nov 2020 15:37:17 |
| User closed query 'Dosing discontinued due to this AE. Please consider updating to Investigational product withdrawn' (Site from CRA). | | 19 Nov 2020 15:37:12 |
| Query 'Dosing discontinued due to this AE. Please consider updating to Investigational product withdrawn' answered with 'updated' (Site from CRA). | Cassandra Zehenny (b) (4) | 19 Nov 2020 15:14:54 |
| User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Per Query Resolution | Cassandra Zehenny (b) (4) | 19 Nov 2020 15:14:47 |
| User opened query 'Dosing discontinued due to this AE. Please consider updating to Investigational product withdrawn' (Site from CRA). | (b) (4), (b) (6) | 19 Nov 2020 01:36:38 |
| DataPoint Un-verified. | | 19 Nov 2020 01:36:22 |
| DataPoint Verified. | | 10 Nov 2020 19:22:48 |
| User entered 'None (NONE)' reason for change: New Information | Joan Siegner (b) (4) | 11 Sep 2020 11:58:12 |
| User closed query 'Data is required. Please complete.' (Site from System). | System | 10 Sep 2020 14:31:16 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 10 Sep 2020 14:31:16 |
| User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: New Information | Heather Douds (b) (4) | 10 Sep 2020 14:31:16 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 04 Sep 2020 21:23:55 |
| User entered empty. | Mikayla Frye (b) (4) | 04 Sep 2020 21:23:55 |

US3552035

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:49:48

None

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) | 19 Nov 2020 01:36:18 |
| DataPoint Un-verified. | (b) (4), (b) (6) | 19 Nov 2020 01:35:07 |
| DataPoint Verified. | | 10 Nov 2020 19:22:48 |
| User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System). | System | 05 Sep 2020 14:30:06 |
| User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System). | System | 04 Sep 2020 21:23:55 |
| User entered '0' | Mikayla Frye (b) (4) (b) (4) | 04 Sep 2020 21:23:55 |

US3552035

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:49:48

[Concomitant Medication](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 10 Nov 2020 19:22:48 |
| User entered '1' reason for change: Data Entry Error | Joan Siegner (b) (4) | 05 Sep 2020 14:30:06 |
| | | |
| User entered '0' | Mikayla Frye (b) (4) | 04 Sep 2020 21:23:55 |
| | (b) (4) | |

US3552035

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:49:48

[Concomitant Procedure](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 10 Nov 2020 19:22:48 |
| User entered '0' | Mikayla Frye (b) (4) | 04 Sep 2020 21:23:55 |
| | (b) (4) | |

US3552035

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:49:48

[Outcome](#)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 10 Nov 2020 19:22:48 |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error | Stanley Doublin (b) (4) | 24 Sep 2020 17:11:59 |
| User closed query 'Data is required. Please complete.' (Site from System). | System | 05 Sep 2020 14:30:06 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 05 Sep 2020 14:30:06 |
| User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error | Joan Siegner (b) (4) | 05 Sep 2020 14:30:06 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 04 Sep 2020 21:23:55 |
| User entered empty. | Mikayla Frye (b) (4) | 04 Sep 2020 21:23:55 |

US3552035

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:49:48

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 10 Nov 2020 19:22:48 |
| User entered empty. | Mikayla Frye (b) (4) | 04 Sep 2020 21:23:55 |
| | (b) (4) | |

US3552035

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:49:48

[Narrative](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 10 Nov 2020 19:22:48 |
| User entered empty. | Mikayla Frye (b) (4) (b) (4) | 04 Sep 2020 21:23:55 |

US3552035

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:49:48

Serious Adverse Event Derived (CSA Programming Field Only)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '0' | System | 04 Sep 2020 21:23:55 |

US3552035

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:49:48

Medically Attended AE Derived (CSA Programming Field Only)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 04 Sep 2020 21:23:55 |

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 11 Aug 2021 22:49:48

[Were any prior/concomitant medications and/or vaccinations taken?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 15:26:23 |
| Data entry locked. | | 03 May 2021 15:13:25 |
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 09 Nov 2020 04:27:52 |
| User entered 'Yes (Y)' | Mikayla Frye (b) (4) (b) (4) | 14 Aug 2020 20:15:21 |

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:49:48

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 10 Nov 2020 22:12:21 |
| User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: OTHER ANXIOLYTICS, PRODUCT: SERTRALINE - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 15 Aug 2020 00:11:48 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 15 Aug 2020 00:11:48 |
| Data point term sent to Coder | System | 14 Aug 2020 20:16:57 |
| User entered 'Sertraline' | Mikayla Frye (b) (4) (b) (4) | 14 Aug 2020 20:16:06 |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:49:48

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 10 Nov 2020 22:12:21 |
| User entered 'No (N)' | Mikayla Frye (b) (4) | 14 Aug 2020 20:16:06 |
| | (b) (4) | |

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:49:48

[Indication](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 10 Nov 2020 22:12:21 |
| User entered 'Anxiety' | Mikayla Frye (b) (4) | 14 Aug 2020 20:16:06 |
| | (b) (4) | |

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:49:48

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 10 Nov 2020 22:12:21 |
| User entered '150' | Mikayla Frye (b) (4) (b) (4) | 14 Aug 2020 20:16:06 |

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:49:48

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 10 Nov 2020 22:12:21 |
| User entered 'mg (mg)' | Mikayla Frye (b) (4) (b) (4) | 14 Aug 2020 20:16:06 |

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:49:48

[If dose unit is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 10 Nov 2020 22:12:21 |
| User entered empty. | Mikayla Frye (b) (4) (b) (4) | 14 Aug 2020 20:16:06 |

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:49:48

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|----------------------|----------------------|
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 10 Nov 2020 22:12:21 |
| User entered 'once daily (QD)' | Mikayla Frye (b) (4) | 14 Aug 2020 20:16:06 |
| | (b) (4) | |

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:49:48

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 10 Nov 2020 22:12:21 |
| User entered empty. | Mikayla Frye (b) (4) (b) (4) | 14 Aug 2020 20:16:06 |

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:49:48

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 10 Nov 2020 22:12:21 |
| User entered 'Oral (ORAL)' | Mikayla Frye (b) (4) (b) (4) | 14 Aug 2020 20:16:06 |

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:49:48

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 10 Nov 2020 22:12:21 |
| User entered empty. | Mikayla Frye (b) (4) | 14 Aug 2020 20:16:06 |
| | (b) (4) | |

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:49:48

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) | 10 Nov 2020 22:12:21 |
| User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). | (b) (4), (b) (6) | 16 Aug 2020 14:05:50 |
| Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'Date is correct as entered.' (Site from System). | Mikayla Frye (b) (4) (b) (4) | 14 Aug 2020 20:33:46 |
| User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). | System | 14 Aug 2020 20:16:06 |
| User entered 'UN UNK 2004' | Mikayla Frye (b) (4) (b) (4) | 14 Aug 2020 20:16:06 |

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:49:48

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 10 Nov 2020 22:12:21 |
| User entered '0' | Mikayla Frye (b) (4) | 14 Aug 2020 20:16:06 |
| | (b) (4) | |

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:49:48

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 10 Nov 2020 22:12:21 |
| User entered 'Yes (Y)' | Mikayla Frye (b) (4) (b) (4) | 14 Aug 2020 20:16:06 |

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:49:48

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 10 Nov 2020 22:12:21 |
| User entered empty. | Mikayla Frye (b) (4) | 14 Aug 2020 20:16:06 |
| | (b) (4) | |

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:49:48

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 10 Nov 2020 22:12:21 |
| User entered 'No (N)' | Mikayla Frye (b) (4) | 14 Aug 2020 20:16:06 |
| | (b) (4) | |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:49:48

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'l' | System | 14 Aug 2020 20:16:06 |

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:49:48

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 14 Aug 2020 20:16:06 |

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:49:48

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 14 Aug 2020 20:16:06 |

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:49:48

[Name of Medication](#)

| Audit | User | Time (GMT) |
|---|----------------------|----------------------|
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 10 Nov 2020 22:12:21 |
| User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: PSYCHOSTIMULANTS, AGENTS USED FOR ADHD AND NOOTROPICS, ATC: CENTRALLY ACTING SYMPATHOMIMETICS, PRODUCT: METHYLPHENIDATE - version WHODrug-Global-B3\202003. | Coder Import (b) (4) | 15 Aug 2020 00:11:52 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003. | Coder Import (b) (4) | 15 Aug 2020 00:11:52 |
| Data point term sent to Coder | System | 14 Aug 2020 20:18:01 |
| User entered 'Methylphenidate' | Mikayla Frye (b) (4) | 14 Aug 2020 20:17:08 |
| | (b) (4) | |

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:49:48

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 10 Nov 2020 22:12:21 |
| User entered 'No (N)' | Mikayla Frye (b) (4) (b) (4) | 14 Aug 2020 20:17:08 |

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:49:48

[Indication](#)

| Audit | User | Time (GMT) |
|---|----------------------|----------------------|
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 10 Nov 2020 22:12:21 |
| User entered 'Attention Deficit Disorder' | Mikayla Frye (b) (4) | 14 Aug 2020 20:17:08 |
| | (b) (4) | |

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:49:48

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 10 Nov 2020 22:12:21 |
| User entered '54' | Mikayla Frye (b) (4) | 14 Aug 2020 20:17:08 |
| | (b) (4) | |

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:49:48

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 10 Nov 2020 22:12:21 |
| User entered 'mg (mg)' | Mikayla Frye (b) (4) (b) (4) | 14 Aug 2020 20:17:08 |

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:49:48

[If dose unit is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 10 Nov 2020 22:12:21 |
| User entered empty. | Mikayla Frye (b) (4) (b) (4) | 14 Aug 2020 20:17:08 |

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:49:48

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|----------------------|----------------------|
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 10 Nov 2020 22:12:21 |
| User entered 'once daily (QD)' | Mikayla Frye (b) (4) | 14 Aug 2020 20:17:08 |
| | (b) (4) | |

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:49:48

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 10 Nov 2020 22:12:21 |
| User entered empty. | Mikayla Frye (b) (4) | 14 Aug 2020 20:17:08 |
| | (b) (4) | |

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:49:48

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 10 Nov 2020 22:12:21 |
| User entered 'Oral (ORAL)' | Mikayla Frye (b) (4) | 14 Aug 2020 20:17:08 |
| | (b) (4) | |

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:49:48

[If route of administration is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 10 Nov 2020 22:12:21 |
| User entered empty. | Mikayla Frye (b) (4) | 14 Aug 2020 20:17:08 |
| | (b) (4) | |

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:49:48

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) | 10 Nov 2020 22:12:21 |
| User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). | (b) (4), (b) (6) | 16 Aug 2020 14:05:54 |
| Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'Date is correct as entered.' (Site from System). | Mikayla Frye (b) (4) (b) (4) | 14 Aug 2020 20:32:32 |
| User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). | System | 14 Aug 2020 20:17:08 |
| User entered 'UN UNK 2005' | Mikayla Frye (b) (4) (b) (4) | 14 Aug 2020 20:17:08 |

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:49:48

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 10 Nov 2020 22:12:21 |
| User entered '0' | Mikayla Frye (b) (4) | 14 Aug 2020 20:17:08 |
| | (b) (4) | |

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:49:48

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 10 Nov 2020 22:12:21 |
| User entered 'Yes (Y)' | Mikayla Frye (b) (4) | 14 Aug 2020 20:17:08 |
| | (b) (4) | |

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:49:48

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 10 Nov 2020 22:12:21 |
| User entered empty. | Mikayla Frye (b) (4) | 14 Aug 2020 20:17:08 |
| | (b) (4) | |

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:49:48

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 10 Nov 2020 22:12:21 |
| User entered 'No (N)' | Mikayla Frye (b) (4) (b) (4) | 14 Aug 2020 20:17:08 |

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:49:48

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'l' | System | 14 Aug 2020 20:17:08 |

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:49:48

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 14 Aug 2020 20:17:08 |

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:49:48

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 14 Aug 2020 20:17:08 |

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:49:48

[Name of Medication](#)

| Audit | User | Time (GMT) |
|---|----------------------|----------------------|
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 10 Nov 2020 22:12:21 |
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: OMEPRAZOLE - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 15 Aug 2020 06:42:16 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 15 Aug 2020 06:42:16 |
| Data point term sent to Coder | System | 14 Aug 2020 21:39:39 |
| Data point term sent to Coder | System | 14 Aug 2020 20:19:05 |
| User entered 'Omeprazole' | Mikayla Frye (b) (4) | 14 Aug 2020 20:18:49 |
| | (b) (4) | |

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:49:48

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 10 Nov 2020 22:12:21 |
| User entered 'No (N)' | Mikayla Frye (b) (4) (b) (4) | 14 Aug 2020 20:18:49 |

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:49:48

[Indication](#)

| Audit | User | Time (GMT) |
|-------------------------------|---------------------------------|----------------------|
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 10 Nov 2020 22:12:21 |
| User entered 'Reflux Disease' | Mikayla Frye (b) (4) (b) (4) | 14 Aug 2020 20:18:49 |

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:49:48

[Dose per administration](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 10 Nov 2020 22:12:21 |
| User closed query 'Data is required. Please complete.' (Site from System). | System | 14 Aug 2020 21:38:41 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 14 Aug 2020 21:38:41 |
| User entered '1' reason for change: Data Entry Error | Mikayla Frye (b) (4) | 14 Aug 2020 21:38:41 |
| | (b) (4) | |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 14 Aug 2020 20:18:49 |
| User entered empty. | Mikayla Frye (b) (4) | 14 Aug 2020 20:18:49 |
| | (b) (4) | |

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:49:48

[Dose unit](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 10 Nov 2020 22:12:21 |
| User closed query 'Data is required. Please complete.' (Site from System). | System | 14 Aug 2020 21:38:47 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 14 Aug 2020 21:38:47 |
| User entered 'tablet (TABLET)' reason for change: Data Entry Error | Mikayla Frye (b) (4) | 14 Aug 2020 21:38:47 |
| | (b) (4) | |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 14 Aug 2020 20:18:49 |
| User entered empty. | Mikayla Frye (b) (4) | 14 Aug 2020 20:18:49 |
| | (b) (4) | |

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:49:48

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 10 Nov 2020 22:12:21 |
| User entered empty. | Mikayla Frye (b) (4) | 14 Aug 2020 20:18:49 |
| | (b) (4) | |

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:49:48

[Frequency](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 10 Nov 2020 22:12:21 |
| User closed query 'Data is required. Please complete.' (Site from System). | System | 14 Aug 2020 21:38:56 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 14 Aug 2020 21:38:56 |
| User entered 'once daily (QD)' reason for change: Data Entry Error | Mikayla Frye (b) (4) | 14 Aug 2020 21:38:56 |
| | (b) (4) | |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 14 Aug 2020 20:18:49 |
| User entered empty. | Mikayla Frye (b) (4) | 14 Aug 2020 20:18:49 |
| | (b) (4) | |

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:49:48

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 10 Nov 2020 22:12:21 |
| User entered empty. | Mikayla Frye (b) (4) | 14 Aug 2020 20:18:49 |
| | (b) (4) | |

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:49:48

[Route of administration](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 10 Nov 2020 22:12:21 |
| User closed query 'Data is required. Please complete.' (Site from System). | System | 14 Aug 2020 21:39:03 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 14 Aug 2020 21:39:03 |
| User entered 'Oral (ORAL)' reason for change: Data Entry Error | Mikayla Frye (b) (4) | 14 Aug 2020 21:39:03 |
| | (b) (4) | |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 14 Aug 2020 20:18:49 |
| User entered empty. | Mikayla Frye (b) (4) | 14 Aug 2020 20:18:49 |
| | (b) (4) | |

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:49:48

[If route of administration is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 10 Nov 2020 22:12:21 |
| User entered empty. | Mikayla Frye (b) (4) | 14 Aug 2020 20:18:49 |
| | (b) (4) | |

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:49:48

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) | 10 Nov 2020 22:12:21 |
| User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). | (b) (4), (b) (6) | 16 Aug 2020 14:05:59 |
| Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'Date is correct as entered.' (Site from System). | Mikayla Frye (b) (4) (b) (4) | 14 Aug 2020 20:32:15 |
| User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). | System | 14 Aug 2020 20:18:49 |
| User entered 'UN UNK 2010' | Mikayla Frye (b) (4) (b) (4) | 14 Aug 2020 20:18:49 |

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:49:48

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 10 Nov 2020 22:12:21 |
| User entered '0' | Mikayla Frye (b) (4) | 14 Aug 2020 20:18:49 |
| | (b) (4) | |

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:49:48

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 10 Nov 2020 22:12:21 |
| User entered 'Yes (Y)' | Mikayla Frye (b) (4) (b) (4) | 14 Aug 2020 20:18:49 |

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:49:48

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 10 Nov 2020 22:12:21 |
| User entered empty. | Mikayla Frye (b) (4) | 14 Aug 2020 20:18:49 |
| | (b) (4) | |

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:49:48

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 10 Nov 2020 22:12:21 |
| User entered 'No (N)' | Mikayla Frye (b) (4) | 14 Aug 2020 20:18:49 |
| | (b) (4) | |

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:49:48

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered 'l' | System | 14 Aug 2020 21:38:56 |
| User entered empty. | System | 14 Aug 2020 20:18:49 |

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:49:48

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered 'l' | System | 14 Aug 2020 21:38:56 |
| User entered empty. | System | 14 Aug 2020 20:18:49 |

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:49:48

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 14 Aug 2020 21:38:56 |
| User entered empty. | System | 14 Aug 2020 20:18:49 |

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:49:48

[Name of Medication](#)

| Audit | User | Time (GMT) |
|---|---------------------------------|--|
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 10 Nov 2020 22:12:21 |
| User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: NAPROXEN - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 06 Oct 2020 17:42:17 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 06 Oct 2020 17:42:17 |
| Data point term sent to Coder Coding entries removed. | System Joan Siegner (b) (4) | 06 Oct 2020 17:41:30 06 Oct 2020 17:40:54 |
| User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: NAPROXEN - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 15 Aug 2020 06:49:17 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 15 Aug 2020 06:49:17 |
| Data point term sent to Coder | System | 14 Aug 2020 20:31:32 |
| Data point term sent to Coder | System | 14 Aug 2020 20:21:10 |
| User entered 'Naproxen' | Mikayla Frye (b) (4) (b) (4) | 14 Aug 2020 20:20:23 |

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:49:48

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 10 Nov 2020 22:12:21 |
| User entered 'No (N)' | Mikayla Frye (b) (4) | 14 Aug 2020 20:20:23 |
| | (b) (4) | |

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:49:48

[Indication](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) | 10 Nov 2020 22:12:21 |
| User closed query ' Per DM CLR: Note there is no Medical History Condition that matches this Con Med indication. Please review Con Med use and add a medical condition and all applicable details to the appropriate medical history eCRF." ' (Site from DM). | (b) (4), (b) (6) | 09 Oct 2020 11:29:04 |
| Query ' Per DM CLR: Note there is no Medical History Condition that matches this Con Med indication. Please review Con Med use and add a medical condition and all applicable details to the appropriate medical history eCRF." ' answered with 'information pending' (Site from DM). | Joan Siegner (b) (4) | 06 Oct 2020 17:42:42 |
| User entered 'BACK PAIN' reason for change: Data Entry Error | Joan Siegner (b) (4) | 06 Oct 2020 17:40:54 |
| User opened query ' Per DM CLR: Note there is no Medical History Condition that matches this Con Med indication. Please review Con Med use and add a medical condition and all applicable details to the appropriate medical history eCRF." ' (Site from DM). | (b) (4), (b) (6) | 05 Oct 2020 13:52:51 |
| User closed query 'Data is required. Please complete.' (Site from System). | System | 14 Aug 2020 20:30:41 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 14 Aug 2020 20:30:41 |
| User entered 'Backpain' reason for change: Data Entry Error | Mikayla Frye (b) (4) | 14 Aug 2020 20:30:41 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 14 Aug 2020 20:20:23 |
| User entered empty. | Mikayla Frye (b) (4) | 14 Aug 2020 20:20:23 |

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:49:48

[Dose per administration](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 10 Nov 2020 22:12:21 |
| User closed query ""Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are various dosage options for this drug. Update Con Med eCRF as appropriate. | | 13 Oct 2020 08:59:11 |
| ' (Site from DM). | | |
| Query ""Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are various dosage options for this drug. Update Con Med eCRF as appropriate. | Joan Siegner (b) (4) | 06 Oct 2020 17:42:34 |
| ' answered with 'dosage unknown; self-reported' (Site from DM). | | |
| User opened query ""Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are various dosage options for this drug. Update Con Med eCRF as appropriate. | (b) (4), (b) (6) | 05 Oct 2020 13:52:54 |
| ' (Site from DM). | | |
| User entered 'I' | Mikayla Frye (b) (4) (b) (4) | 14 Aug 2020 20:20:23 |

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:49:48

[Dose unit](#)

| Audit | User | Time (GMT) |
|--------------------------------|---------------------------------|----------------------|
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 10 Nov 2020 22:12:21 |
| User entered 'tablet (TABLET)' | Mikayla Frye (b) (4) (b) (4) | 14 Aug 2020 20:20:23 |

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:49:48

[If dose unit is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 10 Nov 2020 22:12:21 |
| User entered empty. | Mikayla Frye (b) (4) | 14 Aug 2020 20:20:23 |
| | (b) (4) | |

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:49:48

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|----------------------|----------------------|
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 10 Nov 2020 22:12:21 |
| User entered 'as needed (PRN)' | Mikayla Frye (b) (4) | 14 Aug 2020 20:20:23 |
| | (b) (4) | |

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:49:48

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 10 Nov 2020 22:12:21 |
| User entered empty. | Mikayla Frye (b) (4) | 14 Aug 2020 20:20:23 |
| | (b) (4) | |

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:49:48

[Route of administration](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 10 Nov 2020 22:12:21 |
| User closed query 'Data is required. Please complete.' (Site from System). | System | 14 Aug 2020 20:30:51 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 14 Aug 2020 20:30:51 |
| User entered 'Oral (ORAL)' reason for change: Data Entry Error | Mikayla Frye (b) (4) (b) (4) | 14 Aug 2020 20:30:51 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 14 Aug 2020 20:20:23 |
| User entered empty. | Mikayla Frye (b) (4) (b) (4) | 14 Aug 2020 20:20:23 |

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:49:48

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 10 Nov 2020 22:12:21 |
| User entered empty. | Mikayla Frye (b) (4) (b) (4) | 14 Aug 2020 20:20:23 |

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:49:48

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|---------------------------------|----------------------|
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 10 Nov 2020 22:12:21 |
| User closed query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System). | System | 14 Aug 2020 20:31:05 |
| User entered '11 Aug 2020' reason for change: Data Entry Error | Mikayla Frye (b) (4) (b) (4) | 14 Aug 2020 20:31:05 |
| User opened query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System). | System | 14 Aug 2020 20:20:23 |
| User entered empty. | Mikayla Frye (b) (4) (b) (4) | 14 Aug 2020 20:20:23 |

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:49:48

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 10 Nov 2020 22:12:21 |
| User entered '0' | Mikayla Frye (b) (4) | 14 Aug 2020 20:20:23 |
| | (b) (4) | |

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:49:48

[Ongoing?](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 10 Nov 2020 22:12:21 |
| User closed query 'Data is required. Please complete.' (Site from System). | System | 14 Aug 2020 20:31:13 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 14 Aug 2020 20:31:13 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | Mikayla Frye (b) (4) | 14 Aug 2020 20:31:13 |
| | (b) (4) | |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 14 Aug 2020 20:20:23 |
| User entered empty. | Mikayla Frye (b) (4) | 14 Aug 2020 20:20:23 |
| | (b) (4) | |

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:49:48

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 10 Nov 2020 22:12:21 |
| User entered empty. | Mikayla Frye (b) (4) | 14 Aug 2020 20:20:23 |
| | (b) (4) | |

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:49:48

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 10 Nov 2020 22:12:21 |
| User closed query 'Data is required. Please complete.' (Site from System). | System | 14 Aug 2020 20:31:18 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 14 Aug 2020 20:31:18 |
| User entered 'No (N)' reason for change: Data Entry Error | Mikayla Frye (b) (4) | 14 Aug 2020 20:31:18 |
| | (b) (4) | |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 14 Aug 2020 20:20:23 |
| User entered empty. | Mikayla Frye (b) (4) | 14 Aug 2020 20:20:23 |
| | (b) (4) | |

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:49:48

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 14 Aug 2020 20:20:23 |

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:49:48

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 14 Aug 2020 20:20:23 |

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:49:48

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 14 Aug 2020 20:20:23 |

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:49:48

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 10 Nov 2020 22:12:21 |
| User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: BENZODIAZEPINE RELATED DRUGS, PRODUCT: ESZOPICLONE, PRODUCTSYNONYM: LUNESTA - version WHODrug-Global-B3\202003. | Coder Import (b) (4) | 21 Aug 2020 20:35:31 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003. | Coder Import (b) (4) | 21 Aug 2020 20:35:31 |
| Data point term sent to Coder | System | 21 Aug 2020 20:34:46 |
| User entered 'lunesta' | Mikayla Frye (b) (4) | 21 Aug 2020 20:34:35 |
| | (b) (4) | |

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:49:48

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 10 Nov 2020 22:12:21 |
| User entered 'No (N)' | Mikayla Frye (b) (4) | 21 Aug 2020 20:34:35 |
| | (b) (4) | |

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:49:48

[Indication](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) | 10 Nov 2020 22:12:21 |
| User entered 'insomnia' | (b) (4), (b) (6) | |
| | Mikayla Frye (b) (4) | 21 Aug 2020 20:34:35 |
| | (b) (4) | |

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:49:48

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 10 Nov 2020 22:12:21 |
| User entered '0.5' | Mikayla Frye (b) (4) | 21 Aug 2020 20:34:35 |
| | (b) (4) | |

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:49:48

[Dose unit](#)

| Audit | User | Time (GMT) |
|--------------------------------|----------------------|----------------------|
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 10 Nov 2020 22:12:21 |
| User entered 'tablet (TABLET)' | Mikayla Frye (b) (4) | 21 Aug 2020 20:34:35 |
| | (b) (4) | |

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:49:48

[If dose unit is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 10 Nov 2020 22:12:21 |
| User entered empty. | Mikayla Frye (b) (4) | 21 Aug 2020 20:34:35 |
| | (b) (4) | |

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:49:48

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|----------------------|----------------------|
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 10 Nov 2020 22:12:21 |
| User entered 'as needed (PRN)' | Mikayla Frye (b) (4) | 21 Aug 2020 20:34:35 |
| | (b) (4) | |

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:49:48

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 10 Nov 2020 22:12:21 |
| User entered empty. | Mikayla Frye (b) (4) | 21 Aug 2020 20:34:35 |
| | (b) (4) | |

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:49:48

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 10 Nov 2020 22:12:21 |
| User entered 'Oral (ORAL)' | Mikayla Frye (b) (4) | 21 Aug 2020 20:34:35 |
| | (b) (4) | |

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:49:48

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 10 Nov 2020 22:12:21 |
| User entered empty. | Mikayla Frye (b) (4) | 21 Aug 2020 20:34:35 |
| | (b) (4) | |

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:49:48

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 10 Nov 2020 22:12:21 |
| User entered '13 Aug 2020' | Mikayla Frye (b) (4) | 21 Aug 2020 20:34:35 |
| | (b) (4) | |

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:49:48

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) | 10 Nov 2020 22:12:21 |
| User entered '0' | (b) (4), (b) (6) | |
| | Mikayla Frye (b) (4) | 21 Aug 2020 20:34:35 |
| | (b) (4) | |

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:49:48

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 10 Nov 2020 22:12:21 |
| User entered 'Yes (Y)' | Mikayla Frye (b) (4) | 21 Aug 2020 20:34:35 |
| | (b) (4) | |

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:49:48

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 10 Nov 2020 22:12:21 |
| User entered empty. | Mikayla Frye (b) (4) | 21 Aug 2020 20:34:35 |
| | (b) (4) | |

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:49:48

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 10 Nov 2020 22:12:21 |
| User entered 'No (N)' | Mikayla Frye (b) (4) | 21 Aug 2020 20:34:35 |
| | (b) (4) | |

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:49:48

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 21 Aug 2020 20:34:35 |

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:49:48

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 21 Aug 2020 20:34:35 |

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:49:48

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 21 Aug 2020 20:34:35 |

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:49:48

Name of Medication

| Audit | User | Time (GMT) |
|--|--------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 22 Apr 2021 10:18:14 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Nov 2020 22:12:21 |
| User closed query 'Per MM: Please confirm this medication does not meet exclusion criteria #12 (Has received systemic immunosuppressants or immune-modifying drugs for >14 days in total within 6 months prior to Screening) (for corticosteroids ≥ 20 mg/day of prednisone equivalent).' (Site from DM). Query 'Per MM: Please confirm this medication does not meet exclusion criteria #12 (Has received systemic immunosuppressants or immune-modifying drugs for >14 days in total within 6 months prior to Screening) (for corticosteroids ≥ 20 mg/day of prednisone equivalent).' answered with 'Did not equal >14 days. Tapered dose from 24mg to 4mg over 6 days' (Site from DM). | (b) (4), (b) (6) | 22 Oct 2020 04:22:30 |
| User opened query 'Per MM: Please confirm this medication does not meet exclusion criteria #12 (Has received systemic immunosuppressants or immune-modifying drugs for >14 days in total within 6 months prior to Screening) (for corticosteroids ≥ 20 mg/day of prednisone equivalent).' (Site from DM). | Cassandra Zehenny (b) (4) (b) (4) | 21 Oct 2020 14:47:53 |
| User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOIDS, PRODUCT: PREDNISONE - version WHODrug-Global-B3\202003. | (b) (4), (b) (6) | 20 Oct 2020 15:03:21 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003. | Coder Import (b) (4) (b) (4) | 05 Sep 2020 07:15:44 |
| Data point term sent to Coder | System | 04 Sep 2020 21:20:31 |
| User entered 'prednisone' | Mikayla Frye (b) (4) (b) (4) | 04 Sep 2020 21:20:31 |

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:49:48

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 22 Apr 2021 10:18:14 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Nov 2020 22:12:21 |
| User entered 'No (N)' | Mikayla Frye (b) (4) (b) (4) | 04 Sep 2020 21:20:31 |

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:49:48

[Indication](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 22 Apr 2021 10:18:14 |
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) | 10 Nov 2020 22:12:21 |
| User entered 'shingles' | (b) (4), (b) (6) | 10 Nov 2020 22:12:21 |
| | Mikayla Frye (b) (4) | 04 Sep 2020 21:20:31 |
| | (b) (4) | |

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:49:48

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---|---------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 22 Apr 2021 10:18:14 |
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) | 10 Nov 2020 22:12:21 |
| User entered '24-4' reason for change: New Information | Cassandra Zehenny (b) (4) | 21 Oct 2020 14:47:32 |
| User closed query 'Per DM CLR: Please note, the dosage administered cannot be verified as entered as more than one formulation is available for this medication. Please confirm and update the Dose and Unit fields accordingly. ' (Site from DM). | (b) (4), (b) (6) | 05 Oct 2020 09:09:37 |
| Query 'Per DM CLR: Please note, the dosage administered cannot be verified as entered as more than one formulation is available for this medication. Please confirm and update the Dose and Unit fields accordingly. ' answered with 'tapering dosage' (Site from DM). | Joan Siegner (b) (4) | 03 Oct 2020 17:56:48 |
| User entered '24' reason for change: Data Entry Error | Joan Siegner (b) (4) | 03 Oct 2020 17:56:31 |
| User opened query 'Per DM CLR: Please note, the dosage administered cannot be verified as entered as more than one formulation is available for this medication. Please confirm and update the Dose and Unit fields accordingly. ' (Site from DM). | (b) (4), (b) (6) | 02 Oct 2020 16:17:53 |
| User entered '24-4' | Mikayla Frye (b) (4) | 04 Sep 2020 21:20:31 |

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:49:48

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 22 Apr 2021 10:18:14 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Nov 2020 22:12:21 |
| User entered 'mg (mg)' | Mikayla Frye (b) (4) (b) (4) | 04 Sep 2020 21:20:31 |

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:49:48

[If dose unit is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 22 Apr 2021 10:18:14 |
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) | 10 Nov 2020 22:12:21 |
| User entered empty. | (b) (4), (b) (6) | 10 Nov 2020 22:12:21 |
| | Mikayla Frye (b) (4) | 04 Sep 2020 21:20:31 |
| | (b) (4) | |

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:49:48

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 22 Apr 2021 10:18:14 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Nov 2020 22:12:21 |
| User entered 'once daily (QD)' | Mikayla Frye (b) (4) (b) (4) | 04 Sep 2020 21:20:31 |

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:49:48

If frequency is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 22 Apr 2021 10:18:14 |
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) | 10 Nov 2020 22:12:21 |
| User entered empty. | (b) (4), (b) (6) | 10 Nov 2020 22:12:21 |
| | Mikayla Frye (b) (4) | 04 Sep 2020 21:20:31 |
| | (b) (4) | |

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:49:48

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 22 Apr 2021 10:18:14 |
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) | 10 Nov 2020 22:12:21 |
| User entered 'Oral (ORAL)' | (b) (4), (b) (6) | 10 Nov 2020 22:12:21 |
| | Mikayla Frye (b) (4) | 04 Sep 2020 21:20:31 |
| | (b) (4) | |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:49:48

[If route of administration is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 22 Apr 2021 10:18:14 |
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 10 Nov 2020 22:12:21 |
| User entered empty. | Mikayla Frye (b) (4) (b) (4) | 04 Sep 2020 21:20:31 |

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:49:48

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|--------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 22 Apr 2021 10:18:14 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Nov 2020 22:12:21 |
| User entered '04 Sep 2020' reason for change: Data Entry Error | Cassandra Zehenny (b) (4) (b) (4) | 21 Oct 2020 14:47:32 |
| User entered '14 Aug 2020' | Mikayla Frye (b) (4) (b) (4) | 04 Sep 2020 21:20:31 |

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:49:48

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 22 Apr 2021 10:18:14 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Nov 2020 22:12:21 |
| User entered '0' | Mikayla Frye (b) (4) (b) (4) | 04 Sep 2020 21:20:31 |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:49:48

[Ongoing?](#)

| Audit | User | Time (GMT) |
|--|---------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 22 Apr 2021 10:18:14 |
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) | 10 Nov 2020 22:12:21 |
| User entered 'No (N)' reason for change: New Information | (b) (4), (b) (6) | 10 Nov 2020 22:12:21 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | Cassandra Zehenny (b) (4) | 21 Oct 2020 14:47:32 |
| | (b) (4) | |
| | Joan Siegner (b) (4) | 05 Sep 2020 14:27:37 |
| | | |
| User entered 'No (N)' reason for change: Data Entry Error | Mikayla Frye (b) (4) | 04 Sep 2020 21:20:37 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Mikayla Frye (b) (4) | 04 Sep 2020 21:20:31 |
| | (b) (4) | |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:49:48

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|---------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 22 Apr 2021 10:18:14 |
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) | 10 Nov 2020 22:12:21 |
| User entered '09 Sep 2020' reason for change: New Information | Cassandra Zehenny (b) (4) | 21 Oct 2020 14:47:32 |
| User closed query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System). | System | 05 Sep 2020 14:27:51 |
| User closed query 'Future date has been entered. Please correct.' (Site from System). | System | 05 Sep 2020 14:27:51 |
| User entered empty; reason for change Data Entry Error | Joan Siegner (b) (4) | 05 Sep 2020 14:27:51 |
| User opened query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System). | System | 05 Sep 2020 14:27:37 |
| User closed query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System). | System | 04 Sep 2020 21:20:37 |
| User opened query 'Future date has been entered. Please correct.' (Site from System). | System | 04 Sep 2020 21:20:31 |
| User opened query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System). | System | 04 Sep 2020 21:20:31 |
| User entered '09 Sep 2020' | Mikayla Frye (b) (4) | 04 Sep 2020 21:20:31 |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:49:48

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 22 Apr 2021 10:18:14 |
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) | 10 Nov 2020 22:12:21 |
| User entered 'No (N)' | (b) (4), (b) (6) | 10 Nov 2020 22:12:21 |
| | Mikayla Frye (b) (4) | 04 Sep 2020 21:20:31 |
| | (b) (4) | |

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:49:48

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 22 Apr 2021 10:18:14 |
| User entered 'I' | System | 04 Sep 2020 21:20:31 |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:49:48

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 22 Apr 2021 10:18:14 |
| User entered 'I' | System | 04 Sep 2020 21:20:31 |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:49:48

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 22 Apr 2021 10:18:14 |
| User entered '804 (804)' | System | 04 Sep 2020 21:20:31 |

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:49:48

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 22 Apr 2021 10:18:18 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Nov 2020 22:12:21 |
| User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIVIRALS FOR SYSTEMIC USE, ATC: DIRECT ACTING ANTIVIRALS, ATC: NUCLEOSIDES AND NUCLEOTIDES EXCL. REVERSE TRANSCRIPTASE INHIBITORS, PRODUCT: VALACICLOVIR, PRODUCTSYNONYM: VALACYCLOVIR [VALACICLOVIR] - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 05 Sep 2020 07:32:48 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 05 Sep 2020 07:32:48 |
| Data point term sent to Coder | System | 04 Sep 2020 21:21:32 |
| User entered 'Valacyclovir' | Mikayla Frye (b) (4) (b) (4) | 04 Sep 2020 21:21:31 |

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:49:48

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 22 Apr 2021 10:18:18 |
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) | 10 Nov 2020 22:12:21 |
| User entered 'No (N)' | (b) (4), (b) (6) | 10 Nov 2020 22:12:21 |
| | Mikayla Frye (b) (4) | 04 Sep 2020 21:21:31 |
| | (b) (4) | |

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:49:48

[Indication](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 22 Apr 2021 10:18:18 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Nov 2020 22:12:21 |
| User entered 'shingles' | Mikayla Frye (b) (4) (b) (4) | 04 Sep 2020 21:21:31 |

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:49:48

[Dose per administration](#)

| Audit | User | Time (GMT) |
|--|--------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 22 Apr 2021 10:18:18 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Jan 2021 15:29:41 |
| User closed query 'Per DM CLR Re-Query : Please note the dosage as this is not the expected dosage for this medication. Please review and either correct dosage or provide explanation for alternate dosage of this medication. Please update eCRF as appropriate(e.g. 1 g)' (Site from DM). | | 11 Dec 2020 12:51:30 |
| User closed query 'Per DM CLR: Please review and remove the units from the dose field and add unit of measurement for this medication to the unit field. Update Con Med eCRF as appropriate.' (Site from DM). | | 11 Dec 2020 12:51:27 |
| Query 'Per DM CLR Re-Query : Please note the dosage as this is not the expected dosage for this medication. Please review and either correct dosage or provide explanation for alternate dosage of this medication. Please update eCRF as appropriate(e.g. 1 g)' answered with 'updated' (Site from DM). | | |
| User entered '1000' reason for change: Data Entry Error | Cassandra Zehenny (b) (4) (b) (4) | 09 Dec 2020 15:42:25 |
| Query 'Per DM CLR: Please review and remove the units from the dose field and add unit of measurement for this medication to the unit field. Update Con Med eCRF as appropriate.' answered with 'updated' (Site from DM). | Cassandra Zehenny (b) (4) (b) (4) | 09 Dec 2020 15:42:19 |
| DataPoint Un-verified. | Cassandra Zehenny (b) (4) (b) (4) | 09 Dec 2020 15:41:51 |
| User entered '1' reason for change: Data Entry Error | Cassandra Zehenny (b) (4) (b) (4) | 09 Dec 2020 15:30:39 |
| User opened query 'Per DM CLR Re-Query : Please note the dosage as this is not the expected dosage for this medication. Please review and either correct dosage or provide explanation for alternate dosage of this medication. Please update eCRF as appropriate(e.g. 1 g)' (Site from DM). | (b) (4), (b) (6) | 09 Dec 2020 09:17:16 |

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:49:48

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---|---------------------------------|----------------------|
| User opened query 'Per DM CLR: Please review and remove the units from the dose field and add unit of measurement for this medication to the unit field. Update Con Med eCRF as appropriate.' (Site from DM). | (b) (4), (b) (6) | 09 Dec 2020 09:13:54 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Nov 2020 22:12:21 |
| User closed query 'Per DM CLR: Please review the dose and unit recorded as this is not the standard dose for this medication. Please correct the dosage and unit or provide explanation for alternate dosage.' (Site from DM). | (b) (4), (b) (6) | 28 Oct 2020 05:22:05 |
| Query 'Per DM CLR: Please review the dose and unit recorded as this is not the standard dose for this medication. Please correct the dosage and unit or provide explanation for alternate dosage.' answered with 'done' (Site from DM). | (b) (4), (b) (6) | 26 Oct 2020 17:04:36 |
| User entered '1 mg' reason for change: Data Entry Error | (b) (4), (b) (6) | 26 Oct 2020 17:04:27 |
| User opened query 'Per DM CLR: Please review the dose and unit recorded as this is not the standard dose for this medication. Please correct the dosage and unit or provide explanation for alternate dosage.' (Site from DM). | (b) (4), (b) (6) | 24 Oct 2020 05:16:50 |
| User entered 'I' | Mikayla Frye (b) (4) (b) (4) | 04 Sep 2020 21:21:31 |

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:49:48

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 22 Apr 2021 10:18:18 |
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) | 10 Nov 2020 22:12:21 |
| User entered 'mg (mg)' | (b) (4), (b) (6) | 10 Nov 2020 22:12:21 |
| | Mikayla Frye (b) (4) | 04 Sep 2020 21:21:31 |
| | (b) (4) | |

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:49:48

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 22 Apr 2021 10:18:18 |
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) | 10 Nov 2020 22:12:21 |
| User entered empty. | (b) (4), (b) (6) | |
| | Mikayla Frye (b) (4) | 04 Sep 2020 21:21:31 |
| | (b) (4) | |

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:49:48

[Frequency](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 22 Apr 2021 10:18:18 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Nov 2020 22:12:21 |
| User entered 'three times daily (TID)' | Mikayla Frye (b) (4) (b) (4) | 04 Sep 2020 21:21:31 |

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:49:48

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 22 Apr 2021 10:18:18 |
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) | 10 Nov 2020 22:12:21 |
| User entered empty. | (b) (4), (b) (6) | 10 Nov 2020 22:12:21 |
| | Mikayla Frye (b) (4) | 04 Sep 2020 21:21:31 |
| | (b) (4) | |

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:49:48

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 22 Apr 2021 10:18:18 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Nov 2020 22:12:21 |
| User entered 'Oral (ORAL)' | Mikayla Frye (b) (4) (b) (4) | 04 Sep 2020 21:21:31 |

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:49:48

[If route of administration is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 22 Apr 2021 10:18:18 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Nov 2020 22:12:21 |
| User entered empty. | Mikayla Frye (b) (4) (b) (4) | 04 Sep 2020 21:21:31 |

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:49:48

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 22 Apr 2021 10:18:18 |
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) | 10 Nov 2020 22:12:21 |
| User entered '04 Sep 2020' | (b) (4), (b) (6) | 10 Nov 2020 22:12:21 |
| | Mikayla Frye (b) (4) | 04 Sep 2020 21:21:31 |
| | (b) (4) | |

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:49:48

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 22 Apr 2021 10:18:18 |
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) | 10 Nov 2020 22:12:21 |
| User entered '0' | (b) (4), (b) (6) | 10 Nov 2020 22:12:21 |
| | Mikayla Frye (b) (4) | 04 Sep 2020 21:21:31 |
| | (b) (4) | |

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:49:48

[Ongoing?](#)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 22 Apr 2021 10:18:18 |
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) | 10 Nov 2020 22:12:21 |
| User entered 'No (N)' reason for change: Data Entry Error | Stanley Dublin (b) (4) | 22 Sep 2020 18:40:57 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | Joan Siegner (b) (4) | 05 Sep 2020 14:29:17 |
| User entered 'No (N)' | Mikayla Frye (b) (4) | 04 Sep 2020 21:21:31 |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:49:48

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 22 Apr 2021 10:18:18 |
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 10 Nov 2020 22:12:21 |
| User entered '14 Sep 2020' reason for change: Data Entry Error | Stanley Doublin (b) (4) (b) (4) | 22 Sep 2020 18:40:57 |
| User closed query 'Future date has been entered. Please correct.' (Site from System). | System | 05 Sep 2020 14:29:17 |
| User entered empty; reason for change Data Entry Error | Joan Siegner (b) (4) (b) (4) | 05 Sep 2020 14:29:17 |
| User opened query 'Future date has been entered. Please correct.' (Site from System). | System | 04 Sep 2020 21:21:31 |
| User entered '14 Sep 2020' | Mikayla Frye (b) (4) (b) (4) | 04 Sep 2020 21:21:31 |

US3552035

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:49:48

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 22 Apr 2021 10:18:18 |
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) | 10 Nov 2020 22:12:21 |
| User entered 'No (N)' | (b) (4), (b) (6) | 10 Nov 2020 22:12:21 |
| | Mikayla Frye (b) (4) | 04 Sep 2020 21:21:31 |
| | (b) (4) | |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:49:48

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 22 Apr 2021 10:18:18 |
| User entered '3' | System | 04 Sep 2020 21:21:31 |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:49:48

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 22 Apr 2021 10:18:18 |
| User entered 'I' | System | 04 Sep 2020 21:21:31 |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:49:48

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 22 Apr 2021 10:18:18 |
| User entered '804 (804)' | System | 04 Sep 2020 21:21:31 |

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 11 Aug 2021 22:49:48

[Were any concomitant procedures performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 01 Mar 2021 15:57:01 |
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| User entered 'No (N)' | (b) (4) Heather Douds (b) (4) (b) (4) | 18 Feb 2021 15:57:46 |

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:49:48

Date of dosing discontinuation (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 08:32:11 |
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4) | 11 Nov 2020 18:54:33 |
| User closed query 'Please change date to 08Sep' (Site from CRA). | (b) (4), (b) (6) | 11 Nov 2020 18:54:24 |
| User entered '17 Sep 2020' reason for change: Data Entry Error | Joan Siegner (b) (4) | 11 Nov 2020 17:41:09 |
| Query 'Please change date to 08Sep' answered with 'data corrected' (Site from CRA). | Joan Siegner (b) (4) | 11 Nov 2020 17:24:33 |
| User entered '08 Sep 2020' reason for change: Data Entry Error | Joan Siegner (b) (4) | 11 Nov 2020 17:24:26 |
| User opened query 'Please change date to 08Sep' (Site from CRA). | (b) (4), (b) (6) | 11 Nov 2020 16:32:51 |
| DataPoint Un-verified. | | 10 Nov 2020 22:15:38 |
| DataPoint Verified. | | 10 Nov 2020 22:06:19 |
| User entered '8 Sep 2020' | Heather Douds (b) (4) | 14 Sep 2020 15:32:10 |

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:49:48

[Primary reason for dosing discontinuation](#)

| Audit | User | Time (GMT) |
|---|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 08:32:11 |
| User signature succeeded. | sharon frey (b) (4) (b) (4) | 21 Feb 2021 17:31:36 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Nov 2020 22:06:19 |
| User entered 'AE (specify) (ADVERSE EVENT)' | Heather Douds (b) (4) (b) (4) | 14 Sep 2020 15:32:10 |

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:49:48

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

| Audit | User | Time (GMT) |
|--|---------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 08:32:11 |
| User signature succeeded. | sharon frey (b) (4) | 21 Feb 2021 17:31:36 |
| User closed query 'Per CDM: Please record AE record number instead of details ' (Site from DM). | (b) (4), (b) (6) | 19 Nov 2020 10:02:55 |
| DataPoint Verified. | (b) (4) | 18 Nov 2020 20:03:02 |
| Query 'Per CDM: Please record AE record number instead of details ' answered with 'updated' (Site from DM). | Cassandra Zehenny (b) (4) | 18 Nov 2020 16:17:26 |
| DataPoint Un-verified. | Cassandra Zehenny (b) (4) | 18 Nov 2020 16:17:23 |
| User entered 'AE #1' reason for change: Per Query Resolution | Cassandra Zehenny (b) (4) | 18 Nov 2020 16:17:23 |
| User opened query 'Per CDM: Please record AE record number instead of details ' (Site from DM). | (b) (4), (b) (6) | 18 Nov 2020 16:14:49 |
| DataPoint Verified. | (b) (4) | 10 Nov 2020 22:06:19 |
| User closed query 'Please consider adding Shingles vaccination to Concomitant medication eCRF and also source if not done already. Thank you! ' (Site from CRA). | (b) (4) | 23 Sep 2020 13:40:20 |
| Query 'Please consider adding Shingles vaccination to Concomitant medication eCRF and also source if not done already. Thank you! ' answered with 'subject had diagnosis of shingles infection not vaccination' (Site from CRA). | Stanley Doublin (b) (4) | 22 Sep 2020 18:41:44 |
| User opened query 'Please consider adding Shingles vaccination to Concomitant medication eCRF and also source if not done already. Thank you! ' (Site from CRA). | (b) (4), (b) (6) | 21 Sep 2020 18:18:45 |
| User entered 'Second vaccination held due to diagnosis of shingles infection' | Heather Douds (b) (4) | 14 Sep 2020 15:32:10 |