

US3302105 (Prod: Keystone VitaLink Research - Spartanburg - PPDS)

Generated By: KC Joubran

Generated On: 09 Jun 2021 16:57:13

All time stamps listed in this document are displayed in GMT

US3302105

Form: Participant Creation

Data signed: (b) (4) 19 Feb 2021 18:02:54

Generated On: 09 Jun 2021 16:57:13

[Participant ID](#)

US3302105

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

US3302105

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 18:02:59

Generated On: 09 Jun 2021 16:57:13

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

US3302105

Folder: Screening

Form: Demographics

Data signed: (b) (4) 19 Feb 2021 18:02:59

Generated On: 09 Jun 2021 16:57:13

| | |
|---|--|
| Date of Birth (MMM yyyy) | (b) (6) 1949 |
| Age | 71 |
| Age Units | YEARS |
| Age (Derived) | 71 |
| Sex | Female <input checked="" type="radio"/> Male <input type="radio"/> |
| Ethnicity | Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/> |
| Race (Check All That Apply) | |
| White | True |
| Black | False |
| Asian | False |
| American Indian or Alaska Native | False |
| Native Hawaiian or other Pacific Islander | False |
| Other | False |
| If race is Other, specify _____ | |
| Unknown | False |
| Not reported | False |

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 19 Feb 2021 18:02:59

Generated On: 09 Jun 2021 16:57:13

| | |
|---|--|
| Date of Informed Consent (<i>dd MMM yyyy</i>) | 07 AUG 2020 |
| Month and Year of Informed Consent (derived) | AUG 2020 |
| Year of Informed Consent (derived) | 2020 |
| Protocol Version | Amendment 1 <input checked="" type="radio"/> Amendment 2 <input type="radio"/> Amendment 3 <input type="radio"/> Amendment 4 <input type="radio"/> Amendment 5 <input type="radio"/> |
| Was participant enrolled in the study? | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| If No, indicate reason for screen fail | Withdrew Consent <input type="radio"/> Inclusion/Exclusion <input type="radio"/> Cohort Full <input type="radio"/> Other <input type="radio"/> |
| If reason for screen fail is Other, specify | |
| Was this participant screened previously? | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| If Yes, previous participant number | |
| Enrollment Trigger | 1 |

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 19 Feb 2021 18:02:59

Generated On: 09 Jun 2021 16:57:13

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 19 Feb 2021 18:02:59

Generated On: 09 Jun 2021 16:57:13

Were any significant conditions reported?

Yes ☒
No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 09 Apr 2021 12:37:50

Generated On: 09 Jun 2021 16:57:13

| | |
|---|--|
| Condition | HYPERTENSION |
| Start date (dd MMM yyyy) | UN UNK 2014 |
| 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 2014 |
| Start Year (derived) | 2014 |
| Stop Month and Year (derived) | _____ |
| Stop Year (derived) | _____ |

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 09 Apr 2021 12:37:50

Generated On: 09 Jun 2021 16:57:13

| | |
|---|--|
| Condition | ARTHRITIS |
| Start date (dd MMM yyyy) | UN UNK 1990 |
| 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 1990 |
| Start Year (derived) | 1990 |
| Stop Month and Year (derived) | _____ |
| Stop Year (derived) | _____ |

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 09 Apr 2021 12:37:50

Generated On: 09 Jun 2021 16:57:13

| | |
|---|--|
| Condition | TONSILLITIS |
| Start date (dd MMM yyyy) | UN UNK 1953 |
| 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 1953 |
| Stop date completely unknown | False |
| Start Month and Year (derived) | JAN 1953 |
| Start Year (derived) | 1953 |
| Stop Month and Year (derived) | JAN 1953 |
| Stop Year (derived) | 1953 |

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 09 Apr 2021 12:37:50

Generated On: 09 Jun 2021 16:57:13

| | |
|---|--|
| Condition | POST MENOPAUSAL |
| Start date (dd MMM yyyy) | UN UNK 2000 |
| 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 2000 |
| Start Year (derived) | 2000 |
| Stop Month and Year (derived) | _____ |
| Stop Year (derived) | _____ |

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 09 Apr 2021 12:37:50

Generated On: 09 Jun 2021 16:57:13

| | |
|---|--|
| Condition | TONSILLECTOMY |
| Start date (dd MMM yyyy) | UN UNK 1953 |
| 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 1953 |
| Stop date completely unknown | False |
| Start Month and Year (derived) | JAN 1953 |
| Start Year (derived) | 1953 |
| Stop Month and Year (derived) | JAN 1953 |
| Stop Year (derived) | 1953 |

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 09 Apr 2021 12:37:50

Generated On: 09 Jun 2021 16:57:13

| | |
|---|--|
| Condition | KNEE REPLACEMENT (RIGHT KNEE) |
| Start date (dd MMM yyyy) | UN UNK 2016 |
| 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 2016 |
| Stop date completely unknown | False |
| Start Month and Year (derived) | JAN 2016 |
| Start Year (derived) | 2016 |
| Stop Month and Year (derived) | JAN 2016 |
| Stop Year (derived) | 2016 |

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 09 Apr 2021 12:37:50

Generated On: 09 Jun 2021 16:57:13

| | |
|---|--|
| Condition | KNEE REPLACEMENT (LEFT KNEE) |
| Start date (dd MMM yyyy) | UN UNK 2016 |
| 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 2016 |
| Stop date completely unknown | False |
| Start Month and Year (derived) | JAN 2016 |
| Start Year (derived) | 2016 |
| Stop Month and Year (derived) | JAN 2016 |
| Stop Year (derived) | 2016 |

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 18:02:59

Generated On: 09 Jun 2021 16:57:13

| | |
|---|--------------------------------------|
| Were vital signs assessed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Date of assessment (<i>dd MMM yyyy</i>) | 07 AUG 2020 |
| Time of assessment (<i>00:00-23:59</i>) | 15:58 (24 HR) |
| Vital Signs Date and Time (derived) | 07 AUG 2020 15:58 |
| Height (<i>xxx.x</i>) | 67 in |
| Weight (<i>xxx.x</i>) | 175 lb |
| BMI (<i>xxx.x</i>) | 27.46618 kg/m ² |
| BMI units | KG/M2 |
| Temperature (<i>xxx.x</i>) | ND - Not Done |
| Route of measurement | Oral <input type="radio"/> |
| | Axillary <input type="radio"/> |
| | Other <input type="radio"/> |
| If Other, specify | |
| Pulse (<i>xxx</i>) | ND - Not Done |
| Pulse units | BPM |
| Respiratory Rate (<i>xxx</i>) | ND - Not Done |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (<i>xxx</i>) | ND - Not Done |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (<i>xxx</i>) | ND - Not Done |
| Diastolic Blood Pressure units | MMHG |
| Height (derived) | |
| Weight (derived) | |

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 18:02:59

Generated On: 09 Jun 2021 16:57:13

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

07 AUG 2020

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 19 Feb 2021 18:02:59

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Date of assessment (*dd MMM yyyy*) 07 AUG 2020

Is the participant of childbearing potential? Yes ☐
No ☒

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

If Partner medically sterile or Other, specify _____

If Surgically sterile, date of surgery (*dd MMM yyyy*) _____

Date of surgery unknown False

If Post-menopausal, date of last menstruation (*dd MMM yyyy*) UN UNK 2000

Date of last menstruation unknown False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 19 Feb 2021 18:02:59

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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) 19 Feb 2021 18:02:59

Generated On: 09 Jun 2021 16:57:13

| | |
|--|-------|
| 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) 19 Feb 2021 18:03:10

Generated On: 09 Jun 2021 16:57:13

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

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 19 Feb 2021 18:03:10

Generated On: 09 Jun 2021 16:57:13

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

What was the participant's randomization number? 185056

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 19 Feb 2021 18:03:10

Generated On: 09 Jun 2021 16:57:13

| | |
|--------|---------------|
| 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) 19 Feb 2021 18:03:10

Generated On: 09 Jun 2021 16:57:13

| | |
|-------------------------------------|--|
| Height | ND - Not Done |
| Weight | ND - Not Done |
| Timepoint | Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/> |
| Were vital signs assessed? | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Date of assessment (dd MMM yyyy) | 07 AUG 2020 |
| Time of assessment (00:00-23:59) | 15:58 (24 HR) |
| Vital Signs Date and Time (derived) | 07 AUG 2020 15:58 |
| Temperature (xxx.x) | 97.5 F |
| Route of measurement | Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/> |
| If Other, specify | |
| Pulse (xxx) | 70 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 16 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 135 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 75 mmHg |
| Diastolic Blood Pressure units | MMHG |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 18:03:10

Generated On: 09 Jun 2021 16:57:13

| | |
|-------------------------------------|--|
| 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) | 07 AUG 2020 |
| Time of assessment (00:00-23:59) | 16:56 (24 HR) |
| Vital Signs Date and Time (derived) | 07 AUG 2020 16:56 |
| Temperature (xxx.x) | 97.5 F |
| Route of measurement | Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/> |
| If Other, specify | |
| Pulse (xxx) | 63 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 18 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 146 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 83 mmHg |
| Diastolic Blood Pressure units | MMHG |

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 18:03:10

Generated On: 09 Jun 2021 16:57:13

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) 19 Feb 2021 18:02:59

Generated On: 09 Jun 2021 16:57:13

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) 07 AUG 2020

What was the treatment time? (00:00-23:59) 16:26 (24 HR)

Treatment Date and Time (derived) 07 AUG 2020 16:26

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) 19 Feb 2021 18:03:10

Generated On: 09 Jun 2021 16:57:13

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

07 AUG 2020

Collection time (00:00-23:59)

16:11 (24 HR)

Collection date and time (derived)

07 AUG 2020 16:11

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 19 Feb 2021 18:02:59

Generated On: 09 Jun 2021 16:57:13

| | | | |
|-------------------------------|---------------------------|---------------------------------|------------------------------------|
| Collection date (dd MMM yyyy) | | | 07 AUG 2020 |
| Lab Test | Was the sample collected? | Collection time (00:00 - 23:59) | Collection date and time (derived) |
| Nasopharyngeal Swab 1 | Yes | 16:09 | 07 AUG 2020 16:09 |
| Nasopharyngeal Swab 2 | No | | |

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 18:02:59

Generated On: 09 Jun 2021 16:57:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:57:13

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

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

07 AUG 2020 16:48

PC Open Date & Time

07 AUG 2020 16:46

PC Close Date & Time

07 AUG 2020 19:16

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:57:13

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

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

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time 07 AUG 2020 20:11

PC Close Date & Time 08 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 AUG 2020 20:52

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

09 AUG 2020 22:11

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3302105

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

10 AUG 2020 21:43

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3302105

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:57:13

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

97.4 °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

11 AUG 2020 22:31

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3302105

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3302105

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

13 AUG 2020 23:02

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3302105

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

07 AUG 2020 16:48

PC Open Date & Time

07 AUG 2020 16:46

PC Close Date & Time

07 AUG 2020 19:16

US3302105

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:57:13

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 ☐

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

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

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

Yes ☐

No ☐

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

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

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

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

PC Open Date & Time

07 AUG 2020 20:11

PC Close Date & Time

08 AUG 2020 11:59

US3302105

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:57:13

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

08 AUG 2020 20:51

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3302105

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

09 AUG 2020 22:07

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3302105

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

10 AUG 2020 21:43

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3302105

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

11 AUG 2020 22:30

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3302105

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

DAY 6

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3302105

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

13 AUG 2020 23:00

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3302105

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:57:13

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 ☐

US3302105

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:57:13

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

No ☒

Yes ☐

| | |
|----------------------|-------------------|
| PC Time stamp | 07 AUG 2020 16:49 |
| PC Open Date & Time | 07 AUG 2020 16:46 |
| PC Close Date & Time | 07 AUG 2020 19:16 |

US3302105

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:57:13

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 ☐

US3302105

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:57:13

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

07 AUG 2020 20:11

PC Close Date & Time

08 AUG 2020 11:59

US3302105

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:57:13

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 ☒

US3302105

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:57:13

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 08 AUG 2020 20:52 |
| PC Open Date & Time | 08 AUG 2020 12:00 |
| PC Close Date & Time | 09 AUG 2020 11:59 |

US3302105

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:57:13

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 ☒

US3302105

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:57:13

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 09 AUG 2020 22:07 |
| PC Open Date & Time | 09 AUG 2020 12:00 |
| PC Close Date & Time | 10 AUG 2020 11:59 |

US3302105

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:57:13

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 ☒

US3302105

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:57:13

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 10 AUG 2020 21:44 |
| PC Open Date & Time | 10 AUG 2020 12:00 |
| PC Close Date & Time | 11 AUG 2020 11:59 |

US3302105

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

55 of 2565

US3302105

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:57:13

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

US3302105

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

DAY 6

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

57 of 2565

US3302105

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:57:13

Yes ☐

PC Time stamp

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3302105

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

59 of 2565

US3302105

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:57:13

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 13 AUG 2020 23:01 |
| PC Open Date & Time | 13 AUG 2020 12:00 |
| PC Close Date & Time | 14 AUG 2020 11:59 |

US3302105

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 18:02:59

Generated On: 09 Jun 2021 16:57:13

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 14 AUG 2020

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

Comments

If Contact Not Made, please provide Comments

US3302105

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 18:02:59

Generated On: 09 Jun 2021 16:57:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3302105

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 18:02:55

Generated On: 09 Jun 2021 16:57:13

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

US3302105

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 18:02:55

Generated On: 09 Jun 2021 16:57:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3302105

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 18:02:59

Generated On: 09 Jun 2021 16:57:13

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3302105

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 18:02:59

Generated On: 09 Jun 2021 16:57:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3302105

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 18:05:00

Generated On: 09 Jun 2021 16:57:13

| | |
|---|---|
| Was this visit performed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Visit date (dd MMM yyyy) | 04 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 |

US3302105

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Feb 2021 18:05:00

Generated On: 09 Jun 2021 16:57:13

| | |
|-------------------------------------|---|
| 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) | 04 SEP 2020 |
| Time of assessment (00:00-23:59) | 08:07 (24 HR) |
| Vital Signs Date and Time (derived) | 04 SEP 2020 08:07 |
| Temperature (xxx.x) | 98.6 F |
| Route of measurement | Oral <input checked="" type="radio"/> |
| | Axillary <input type="radio"/> |
| | Other <input type="radio"/> |
| If Other, specify | |
| Pulse (xxx) | 77 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 16 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 135 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 93 mmHg |
| Diastolic Blood Pressure units | MMHG |

US3302105

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 18:05:00

Generated On: 09 Jun 2021 16:57:13

| | |
|-------------------------------------|---|
| Timepoint | Pre-Dose <input type="checkbox"/> |
| | Post-Dose <input checked="" type="checkbox"/> |
| Were vital signs assessed? | Yes <input checked="" type="checkbox"/> |
| | No <input type="checkbox"/> |
| Date of assessment (dd MMM yyyy) | 04 SEP 2020 |
| Time of assessment (00:00-23:59) | 09:07 (24 HR) |
| Vital Signs Date and Time (derived) | 04 SEP 2020 09:07 |
| Temperature (xxx.x) | 98.6 F |
| Route of measurement | Oral <input checked="" type="checkbox"/> |
| | Axillary <input type="checkbox"/> |
| | Other <input type="checkbox"/> |
| If Other, specify | |
| Pulse (xxx) | 65 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 18 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 146 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 83 mmHg |
| Diastolic Blood Pressure units | MMHG |

US3302105

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 18:05:00

Generated On: 09 Jun 2021 16:57:13

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

04 SEP 2020

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

US3302105

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 18:05:00

Generated On: 09 Jun 2021 16:57:13

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) 04 SEP 2020

What was the treatment time? (00:00-23:59) 08:37 (24 HR)

Treatment Date and Time (derived) 04 SEP 2020 08:37

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

US3302105

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 18:05:00

Generated On: 09 Jun 2021 16:57:13

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

04 SEP 2020

Collection time (00:00-23:59)

08:20 (24 HR)

Collection date and time (derived)

04 SEP 2020 08:20

US3302105

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 19 Feb 2021 18:03:10

Generated On: 09 Jun 2021 16:57:13

| Collection date (dd MMM yyyy) | | | 04 SEP 2020 |
|-------------------------------|---------------------------|---------------------------------|------------------------------------|
| Lab Test | Was the sample collected? | Collection time (00:00 - 23:59) | Collection date and time (derived) |
| Nasopharyngeal Swab 1 | Yes | 08:17 | 04 SEP 2020 08:17 |
| Nasopharyngeal Swab 2 | Yes | 08:17 | 04 SEP 2020 08:17 |

US3302105

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 18:05:00

Generated On: 09 Jun 2021 16:57:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3302105

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

04 SEP 2020 08:59

PC Open Date & Time

04 SEP 2020 08:57

PC Close Date & Time

04 SEP 2020 11:27

US3302105

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:57:13

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

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

Yes ☐
No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

04 SEP 2020 12:22

PC Close Date & Time

05 SEP 2020 11:59

US3302105

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

05 SEP 2020 19:05

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3302105

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

06 SEP 2020 22:07

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3302105

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 SEP 2020 06:50

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3302105

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:57:13

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

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3302105

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:57:13

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.

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

10 SEP 2020 06:30

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3302105

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:57:13

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

95.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

11 SEP 2020 07:41

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3302105

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

04 SEP 2020 09:00

PC Open Date & Time

04 SEP 2020 08:57

PC Close Date & Time

04 SEP 2020 11:27

US3302105

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:57:13

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 ☐

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

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

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

Yes ☐

No ☐

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

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

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

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

PC Open Date & Time

04 SEP 2020 12:22

PC Close Date & Time

05 SEP 2020 11:59

US3302105

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:57:13

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

05 SEP 2020 19:05

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3302105

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:57:13

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

06 SEP 2020 22:07

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3302105

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:57:13

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

08 SEP 2020 06:51

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3302105

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

DAY 5

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3302105

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:57:13

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

10 SEP 2020 06:31

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3302105

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:57:13

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

11 SEP 2020 07:41

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3302105

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:57:13

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 ☐

US3302105

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:57:13

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

No ☒

Yes ☐

| | |
|----------------------|-------------------|
| PC Time stamp | 04 SEP 2020 09:01 |
| PC Open Date & Time | 04 SEP 2020 08:57 |
| PC Close Date & Time | 04 SEP 2020 11:27 |

US3302105

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:57:13

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 ☐

US3302105

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:57:13

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

04 SEP 2020 12:22

PC Close Date & Time

05 SEP 2020 11:59

US3302105

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:57:13

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 ☒

US3302105

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:57:13

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 05 SEP 2020 19:06 |
| PC Open Date & Time | 05 SEP 2020 12:00 |
| PC Close Date & Time | 06 SEP 2020 11:59 |

US3302105

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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97 of 2565

EAB) (1725)

US3302105

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:57:13

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 06 SEP 2020 22:08 |
| PC Open Date & Time | 06 SEP 2020 12:00 |
| PC Close Date & Time | 07 SEP 2020 11:59 |

US3302105

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:57:13

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 ☒

US3302105

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:57:13

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 08 SEP 2020 06:51 |
| PC Open Date & Time | 07 SEP 2020 12:00 |
| PC Close Date & Time | 08 SEP 2020 11:59 |

US3302105

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:57:13

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 ☐

US3302105

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:57:13

Yes ☐

PC Time stamp

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3302105

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:57:13

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 ☒

US3302105

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:57:13

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 10 SEP 2020 06:31 |
| PC Open Date & Time | 09 SEP 2020 12:00 |
| PC Close Date & Time | 10 SEP 2020 11:59 |

US3302105

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:57:13

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 ☒

US3302105

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:57:13

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 11 SEP 2020 07:42 |
| PC Open Date & Time | 10 SEP 2020 12:00 |
| PC Close Date & Time | 11 SEP 2020 11:59 |

US3302105

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 18:02:59

Generated On: 09 Jun 2021 16:57:13

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3302105

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 18:02:59

Generated On: 09 Jun 2021 16:57:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3302105

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 18:02:59

Generated On: 09 Jun 2021 16:57:13

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3302105

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 18:02:59

Generated On: 09 Jun 2021 16:57:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3302105

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 18:02:59

Generated On: 09 Jun 2021 16:57:13

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3302105

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 18:02:59

Generated On: 09 Jun 2021 16:57:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3302105

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 18:05:00

Generated On: 09 Jun 2021 16:57:13

| | |
|---|---|
| Was this visit performed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Visit date (dd MMM yyyy) | 06 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 |

US3302105

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 18:05:00

Generated On: 09 Jun 2021 16:57:13

| | |
|-------------------------------------|---------------------------------------|
| Were vital signs assessed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Date of assessment (dd MMM yyyy) | 06 OCT 2020 |
| Time of assessment (00:00-23:59) | 17:20 (24 HR) |
| Vital Signs Date and Time (derived) | 06 OCT 2020 17:20 |
| Temperature (xxx.x) | 98.6 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) | 18 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 155 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 80 mmHg |
| Diastolic Blood Pressure units | MMHG |
| Height (derived) | |
| Weight (derived) | |

US3302105

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 18:05:00

Generated On: 09 Jun 2021 16:57:13

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

06 OCT 2020

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

US3302105

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 18:05:00

Generated On: 09 Jun 2021 16:57:13

| | |
|--|--------------------------------------|
| Was the sample collected? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Collection date (<i>dd MMM yyyy</i>) | 06 OCT 2020 |
| Collection time (<i>00:00-23:59</i>) | 17:22 (24 HR) |
| Collection date and time (derived) | 06 OCT 2020 17:22 |

US3302105

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 18:05:00

Generated On: 09 Jun 2021 16:57:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3302105

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

| | |
|---|--|
| TIMEPOINT | DAY 64 |
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Date and time of submission | 08 OCT 2020 18:19:59 |
| Patient Cloud Open Date & Time | 07 OCT 2020 00:01 |
| Patient Cloud Close Date & Time | 11 OCT 2020 23:59 |

US3302105

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

| TIMEPOINT | DAY 71 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input checked="" type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input checked="" type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | False |
| Chills | False |
| Cough | False |
| Shortness of breath | False |
| Difficulty breathing | False |
| Fatigue | False |
| Muscle aches | False |
| Body aches | False |
| Headache | False |
| New loss of taste | False |
| New loss of smell | False |
| Sore throat | False |
| Congestion | False |
| Runny nose | False |
| Nausea | True |
| Vomiting | True |
| Diarrhea | True |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Date and time of submission | 16 OCT 2020 11:29:08 |
| Patient Cloud Open Date & Time | 14 OCT 2020 00:01 |
| Patient Cloud Close Date & Time | 18 OCT 2020 23:59 |

US3302105

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

| TIMEPOINT | DAY 78 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Date and time of submission | 23 OCT 2020 15:16:51 |
| Patient Cloud Open Date & Time | 21 OCT 2020 00:01 |
| Patient Cloud Close Date & Time | 25 OCT 2020 23:59 |

US3302105

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

| 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 | 08 NOV 2020 22:21:20 |
| Patient Cloud Open Date & Time | 04 NOV 2020 00:01 |
| Patient Cloud Close Date & Time | 08 NOV 2020 23:59 |

US3302105

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

| 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 <input checked="" type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Date and time of submission | 12 NOV 2020 12:16:38 |
| Patient Cloud Open Date & Time | 11 NOV 2020 00:01 |
| Patient Cloud Close Date & Time | 15 NOV 2020 23:59 |

US3302105

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

| TIMEPOINT | DAY 106 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature \geq 100.4°F/38°C) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |

US3302105

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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

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

Date and time of submission

Patient Cloud Open Date & Time

18 NOV 2020 00:01

Patient Cloud Close Date & Time

22 NOV 2020 23:59

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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

19 NOV 2020 21:55:40

Patient Cloud Open Date & Time

15 NOV 2020 00:01

Patient Cloud Close Date & Time

19 NOV 2020 23:59

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

| TIMEPOINT | DAY 110 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input 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"/> |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

26 NOV 2020 23:59

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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

03 DEC 2020 16:14:15

Patient Cloud Open Date & Time

29 NOV 2020 00:01

Patient Cloud Close Date & Time

03 DEC 2020 23:59

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

| 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 | 09 DEC 2020 20:34:44 |
| Patient Cloud Open Date & Time | 06 DEC 2020 00:01 |
| Patient Cloud Close Date & Time | 10 DEC 2020 23:59 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

| TIMEPOINT | DAY 131 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Date and time of submission | 16 DEC 2020 16:03:01 |
| Patient Cloud Open Date & Time | 13 DEC 2020 00:01 |
| Patient Cloud Close Date & Time | 17 DEC 2020 23:59 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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

21 DEC 2020 09:18:11

Patient Cloud Open Date & Time

20 DEC 2020 00:01

Patient Cloud Close Date & Time

24 DEC 2020 23:59

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 DEC 2020 11:18:45

Patient Cloud Open Date & Time

27 DEC 2020 00:01

Patient Cloud Close Date & Time

31 DEC 2020 23:59

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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

04 JAN 2021 09:31:56

Patient Cloud Open Date & Time

03 JAN 2021 00:01

Patient Cloud Close Date & Time

07 JAN 2021 23:59

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

12 JAN 2021 12:59:02

Patient Cloud Open Date & Time

10 JAN 2021 00:01

Patient Cloud Close Date & Time

14 JAN 2021 23:59

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

| TIMEPOINT | DAY 166 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input checked="" type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Date and time of submission | 18 JAN 2021 09:23:37 |
| Patient Cloud Open Date & Time | 17 JAN 2021 00:01 |
| Patient Cloud Close Date & Time | 21 JAN 2021 23:59 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

| 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 <input checked="" type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input checked="" type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Date and time of submission | 27 JAN 2021 06:40:36 |
| Patient Cloud Open Date & Time | 24 JAN 2021 00:01 |
| Patient Cloud Close Date & Time | 28 JAN 2021 23:59 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

| TIMEPOINT | DAY 180 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Date and time of submission | 01 FEB 2021 08:52:32 |
| Patient Cloud Open Date & Time | 31 JAN 2021 00:01 |
| Patient Cloud Close Date & Time | 04 FEB 2021 23:59 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

09 FEB 2021 09:43:11

Patient Cloud Open Date & Time

07 FEB 2021 00:01

Patient Cloud Close Date & Time

11 FEB 2021 23:59

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

| TIMEPOINT | DAY 194 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Date and time of submission | 16 FEB 2021 21:48:48 |
| Patient Cloud Open Date & Time | 14 FEB 2021 00:01 |
| Patient Cloud Close Date & Time | 18 FEB 2021 23:59 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

| TIMEPOINT | DAY 201 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input checked="" type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input checked="" type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/> |
| Date and time of submission | 21 FEB 2021 15:34:48 |
| Patient Cloud Open Date & Time | 21 FEB 2021 00:01 |
| Patient Cloud Close Date & Time | 25 FEB 2021 23:59 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

| | |
|---|--|
| TIMEPOINT | DAY 208 |
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input 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 MAR 2021 15:09:45 |
| Patient Cloud Open Date & Time | 28 FEB 2021 00:01 |
| Patient Cloud Close Date & Time | 04 MAR 2021 23:59 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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

07 MAR 2021 21:31:42

Patient Cloud Open Date & Time

07 MAR 2021 00:01

Patient Cloud Close Date & Time

11 MAR 2021 23:59

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

| 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 <input checked="" type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Date and time of submission | 15 MAR 2021 15:34:53 |
| Patient Cloud Open Date & Time | 14 MAR 2021 00:01 |
| Patient Cloud Close Date & Time | 18 MAR 2021 23:59 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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

23 MAR 2021 17:19:00

Patient Cloud Open Date & Time

21 MAR 2021 00:01

Patient Cloud Close Date & Time

25 MAR 2021 23:59

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

DAY 236

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

29 MAR 2021 14:14:19

Patient Cloud Open Date & Time

28 MAR 2021 00:01

Patient Cloud Close Date & Time

01 APR 2021 23:59

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

| TIMEPOINT | DAY 243 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input checked="" type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Date and time of submission | 05 APR 2021 09:35:04 |
| Patient Cloud Open Date & Time | 04 APR 2021 00:01 |
| Patient Cloud Close Date & Time | 08 APR 2021 23:59 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

DAY 250

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

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

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

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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

| | |
|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 11 APR 2021 00:01 |
| Patient Cloud Close Date & Time | 15 APR 2021 23:59 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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

19 APR 2021 16:50:44

Patient Cloud Open Date & Time

18 APR 2021 00:01

Patient Cloud Close Date & Time

22 APR 2021 23:59

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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

27 APR 2021 20:59:58

Patient Cloud Open Date & Time

25 APR 2021 00:01

Patient Cloud Close Date & Time

29 APR 2021 23:59

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

DAY 271

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 MAY 2021 20:00:53

Patient Cloud Open Date & Time

02 MAY 2021 00:01

Patient Cloud Close Date & Time

06 MAY 2021 23:59

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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 ☐

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

20 MAY 2021 23:59

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

DAY 292

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

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

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

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

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

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

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

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

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

| 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"/> |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

03 JUN 2021 23:59

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

| 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"/> |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

10 JUN 2021 23:59

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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 ☐

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

17 JUN 2021 23:59

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

| 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"/> |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

24 JUN 2021 23:59

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

DAY 327

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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

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

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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

[Patient Cloud Close Date & Time](#)

08 JUL 2021 23:59

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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

| | |
|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 11 JUL 2021 00:01 |
| Patient Cloud Close Date & Time | 15 JUL 2021 23:59 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

| TIMEPOINT | DAY 348 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

22 JUL 2021 23:59

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

DAY 355

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

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

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

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

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

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

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

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

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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

[Patient Cloud Close Date & Time](#)

29 JUL 2021 23:59

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

| 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"/> |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

05 AUG 2021 23:59

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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 ☐

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

12 AUG 2021 23:59

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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 ☐

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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

| | |
|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 15 AUG 2021 00:01 |
| Patient Cloud Close Date & Time | 19 AUG 2021 23:59 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

DAY 383

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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

| | |
|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 22 AUG 2021 00:01 |
| Patient Cloud Close Date & Time | 26 AUG 2021 23:59 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

| 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"/> |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

02 SEP 2021 23:59

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

DAY 397

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

| 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"/> |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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

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

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

| 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"/> |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

23 SEP 2021 23:59

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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

| | |
|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 26 SEP 2021 00:01 |
| Patient Cloud Close Date & Time | 30 SEP 2021 23:59 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

| 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"/> |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

DAY 432

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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

| | |
|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 10 OCT 2021 00:01 |
| Patient Cloud Close Date & Time | 14 OCT 2021 23:59 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

| 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"/> |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

| 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"/> |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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

| | |
|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 24 OCT 2021 00:01 |
| Patient Cloud Close Date & Time | 28 OCT 2021 23:59 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

DAY 453

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

04 NOV 2021 23:59

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

| 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"/> |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

DAY 474

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

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

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

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

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

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

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

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

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

25 NOV 2021 23:59

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

| 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"/> |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

02 DEC 2021 23:59

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

| 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"/> |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

DAY 495

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

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

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

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

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

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

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

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

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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 ☐

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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

| | |
|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 19 DEC 2021 00:01 |
| Patient Cloud Close Date & Time | 23 DEC 2021 23:59 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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 ☐

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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

[Patient Cloud Close Date & Time](#)

30 DEC 2021 23:59

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

DAY 516

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JAN 2022 23:59

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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 ☐

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

| 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"/> |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JAN 2022 23:59

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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 ☐

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

| 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"/> |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

DAY 551

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

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

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

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

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

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

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

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

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

10 FEB 2022 23:59

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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 ☐

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

17 FEB 2022 23:59

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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 ☐

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

24 FEB 2022 23:59

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

DAY 572

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

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

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

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

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

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

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

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

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

03 MAR 2022 23:59

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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 ☐

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

10 MAR 2022 23:59

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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 ☐

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

17 MAR 2022 23:59

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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 ☐

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

24 MAR 2022 23:59

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

| 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"/> |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

31 MAR 2022 23:59

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

| 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"/> |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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

[Patient Cloud Close Date & Time](#)

07 APR 2022 23:59

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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 ☐

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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

[Patient Cloud Close Date & Time](#)

14 APR 2022 23:59

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

21 APR 2022 23:59

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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

| | |
|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 24 APR 2022 00:01 |
| Patient Cloud Close Date & Time | 28 APR 2022 23:59 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

05 MAY 2022 23:59

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

DAY 642

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2022 23:59

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

| TIMEPOINT | DAY 649 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

19 MAY 2022 23:59

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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 ☐

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

26 MAY 2022 23:59

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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 ☐

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2022 23:59

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

09 JUN 2022 23:59

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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 ☐

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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

| | |
|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 12 JUN 2022 00:01 |
| Patient Cloud Close Date & Time | 16 JUN 2022 23:59 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

DAY 684

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

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

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

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

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

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

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

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

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

23 JUN 2022 23:59

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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

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

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

| 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"/> |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

07 JUL 2022 23:59

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

| 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"/> |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

14 JUL 2022 23:59

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

DAY 712

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

21 JUL 2022 23:59

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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 ☐ 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 ☐

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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

[Patient Cloud Close Date & Time](#)

28 JUL 2022 23:59

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

| 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"/> |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2022 23:59

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

DAY 733

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

11 AUG 2022 23:59

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

| 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"/> |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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

Date and time of submission

| | |
|--|-------------------|
| Patient Cloud Open Date & Time | 14 AUG 2022 00:01 |
|--|-------------------|

| | |
|---|-------------------|
| Patient Cloud Close Date & Time | 18 AUG 2022 23:59 |
|---|-------------------|

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

| 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"/> |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

25 AUG 2022 23:59

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

| 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"/> |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2022 23:59

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

| 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"/> |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

08 SEP 2022 23:59

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

| 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"/> |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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

| | |
|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 11 SEP 2022 00:01 |
| Patient Cloud Close Date & Time | 15 SEP 2022 23:59 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

DAY 775

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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

| | |
|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 18 SEP 2022 00:01 |
| Patient Cloud Close Date & Time | 22 SEP 2022 23:59 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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 ☐

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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

| | |
|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 25 SEP 2022 00:01 |
| Patient Cloud Close Date & Time | 29 SEP 2022 23:59 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

DAY 789

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

06 OCT 2022 23:59

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

| 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"/> |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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

| | |
|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 09 OCT 2022 00:01 |
| Patient Cloud Close Date & Time | 13 OCT 2022 23:59 |

US3302105

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 16:57:13

| 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 | | 03 MAR 2021 15:10:00 |

US3302105

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 18:02:59

Generated On: 09 Jun 2021 16:57:13

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

30 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3302105

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 18:02:59

Generated On: 09 Jun 2021 16:57:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3302105

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 18:02:55

Generated On: 09 Jun 2021 16:57:13

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

4 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3302105

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 18:02:55

Generated On: 09 Jun 2021 16:57:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3302105

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 18:02:55

Generated On: 09 Jun 2021 16:57:13

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

4 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3302105

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 18:02:55

Generated On: 09 Jun 2021 16:57:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3302105

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 18:02:55

Generated On: 09 Jun 2021 16:57:13

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

02 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3302105

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 18:02:55

Generated On: 09 Jun 2021 16:57:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3302105

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 03 Mar 2021 18:51:47

Generated On: 09 Jun 2021 16:57:13

| | |
|---|---|
| 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 |

US3302105

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 02 Apr 2021 15:49:48

Generated On: 09 Jun 2021 16:57:13

| | |
|---|---------------------------------------|
| Were vital signs assessed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Date of assessment (<i>dd MMM yyyy</i>) | 02 MAR 2021 |
| Time of assessment (<i>00:00-23:59</i>) | 08:06 (24 HR) |
| Vital Signs Date and Time (derived) | 02 MAR 2021 08:06 |
| Temperature (<i>xxx.x</i>) | 97.8 F |
| Route of measurement | Oral <input checked="" type="radio"/> |
| | Axillary <input type="radio"/> |
| | Other <input type="radio"/> |
| If Other, specify | |
| Pulse (<i>xxx</i>) | 67 beats/min |
| Pulse units | BPM |
| Respiratory Rate (<i>xxx</i>) | 18 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (<i>xxx</i>) | 139 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (<i>xxx</i>) | 78 mmHg |
| Diastolic Blood Pressure units | MMHG |
| Height (derived) | |
| Weight (derived) | |

US3302105

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 03 Mar 2021 18:51:47

Generated On: 09 Jun 2021 16:57:13

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

02 MAR 2021

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

US3302105

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 03 Mar 2021 18:51:47

Generated On: 09 Jun 2021 16:57:13

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

02 MAR 2021

Collection time (00:00-23:59)

08:13 (24 HR)

Collection date and time (derived)

02 MAR 2021 08:13

US3302105

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 03 Mar 2021 18:51:47

Generated On: 09 Jun 2021 16:57:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3302105

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 15:49:48

Generated On: 09 Jun 2021 16:57:13

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

30 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3302105

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 15:49:48

Generated On: 09 Jun 2021 16:57:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3302105

Folder: Safety Call Day 269 (1)

Form: Safety Call

Data signed: (b) (4) 30 Apr 2021 17:27:11

Generated On: 09 Jun 2021 16:57:13

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3302105

Folder: Safety Call Day 269 (1)

Form: Continuing

Data signed: (b) (4) 30 Apr 2021 17:27:11

Generated On: 09 Jun 2021 16:57:13

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Safety Call Day 299 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:57:13

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

US3302105

Folder: Safety Call Day 299 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:57:13

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3302105

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 16:57:13

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

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Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 16:57:13

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3302105

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

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 18:02:55

Generated On: 09 Jun 2021 16:57:13

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

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

Form: Unblinding

Data signed: (b) (4) 20 Apr 2021 17:48:52

Generated On: 09 Jun 2021 16:57:13

Date of updated informed consent (dd MMM yyyy) 07 JAN 2021

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

Was the participant unblinded? Yes ☒ No ☐

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

Date of unblinding (dd MMM yyyy) 07 JAN 2021

Participant randomization assignment mRNA-1273 ☒ Placebo ☐

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

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

Will participant receive mRNA-1273? Yes ☐ No ☒

Placebo Only Flag _____
Continuing with mRNA-1273 _____

US3302105

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 18:02:55

Generated On: 09 Jun 2021 16:57:13

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

07 JAN 2021

Collection time (00:00-23:59)

15:22 (24 HR)

Collection date and time (derived)

07 JAN 2021 15:22

US3302105

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 19 Feb 2021 18:02:55

Generated On: 09 Jun 2021 16:57:13

| | |
|------------------------------------|--------------------------------------|
| Was the sample collected? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Collection date (dd MMM yyyy) | 07 JAN 2021 |
| Collection time (00:00 - 23:59) | 15:20 |
| Collection Date and Time (derived) | 07 JAN 2021 15:20 |

US3302105

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 19 Feb 2021 18:02:54

Generated On: 09 Jun 2021 16:57:13

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3302105

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 29 Apr 2021 12:33:04

Generated On: 09 Jun 2021 16:57:13

AEID

Adverse event

TOOTH ABSCESS

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

18 JAN 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

30 JAN 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 29 Apr 2021 12:33:04

Generated On: 09 Jun 2021 16:57:13

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

US3302105

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 29 Apr 2021 12:33:04

Generated On: 09 Jun 2021 16:57:13

| | |
|--|--|
| AEID | USA-US087-2021-MRNA-1273-P30 1000020 |
| Adverse event | MYOCARDIAL INFARCTION |
| 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) | 19 FEB 2021 |
| Start time (00:00-23:59) | |
| AE start date and time (derived) | |
| Ongoing? | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| If not Ongoing, end date (dd MMM yyyy) | 19 FEB 2021 |
| End time (00:00-23:59) | |
| AE End Date and Time (derived) | |
| Severity | Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/> |
| Is the adverse event serious? | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| AE is serious due To (check all that apply) | |
| Death | False |
| Life threatening | False |
| Requires inpatient or prolongation of existing Hospitalization | True |
| Hospital Admission Date (dd MMM yyyy) | 19 FEB 2021 |
| Hospital Discharge Date (dd MMM yyyy) | 22 FEB 2021 |
| Admitted to ICU? | Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/> |

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 29 Apr 2021 12:33:04

Generated On: 09 Jun 2021 16:57:13

| | |
|--|---|
| Number of Days in ICU | |
| Persistent or significant disability or incapacity | False |
| Congenital anomaly or birth defect | False |
| Other medically important event | False |
| Relationship to investigational product | Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/> |
| Relationship to Study Procedure | Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/> |
| Action taken with investigational product | None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/> |
| Other action taken (check all that apply) | |
| None | True |
| Concomitant Medication | False |
| Concomitant Procedure | False |
| Outcome | Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/> |
| If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: | |
| Narrative | |

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 29 Apr 2021 12:33:04

Generated On: 09 Jun 2021 16:57:13

SPOUSE CALLED STATING
WIFE SUFFERED AN MI WHILE
ON VACATION SNOW SKIING,
SPOUSE STATES WIFE IS FINE,
HAD NO BLOCKAGES AND
THEY'RE UNSURE WHY MI
OCCURRED.

4/5/2021: SUBJECT'S MEDICAL
RECORDS REGARDING
PREVIOUSLY REPORTED SAE
HAS BEEN
RECEIVED/REVIEWED. ALL
CON MEDS, MEDICAL HISTORY,
AND CON PROCEDURES LISTS
UPDATED IN SOURCE AND EDC.
IRB WAS UPDATED AFTER
REVIEW.

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

US3302105

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 29 Apr 2021 12:33:04

Generated On: 09 Jun 2021 16:57:13

| | |
|--|--|
| AEID | |
| Adverse event | CARDIOMYOPATHY |
| 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) | 22 FEB 2021 |
| Start time (00:00-23:59) | |
| AE start date and time (derived) | |
| Ongoing? | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| If not Ongoing, end date (dd MMM yyyy) | |
| End time (00:00-23:59) | |
| AE End Date and Time (derived) | |
| Severity | Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/> |
| Is the adverse event serious? | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| AE is serious due To (check all that apply) | |
| Death | False |
| Life threatening | False |
| Requires inpatient or prolongation of existing Hospitalization | False |
| Hospital Admission Date (dd MMM yyyy) | |
| Hospital Discharge Date (dd MMM yyyy) | |
| Admitted to ICU? | Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/> |
| Number of Days in ICU | |

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 29 Apr 2021 12:33:04

Generated On: 09 Jun 2021 16:57:13

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

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 29 Apr 2021 12:33:04

Generated On: 09 Jun 2021 16:57:13

| | |
|--|--|
| AEID | |
| Adverse event | CONGESTIVE HEART FAILURE |
| 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) | 22 FEB 2021 |
| Start time (00:00-23:59) | |
| AE start date and time (derived) | |
| Ongoing? | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| If not Ongoing, end date (dd MMM yyyy) | |
| End time (00:00-23:59) | |
| AE End Date and Time (derived) | |
| Severity | Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/> |
| Is the adverse event serious? | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| AE is serious due To (check all that apply) | |
| Death | False |
| Life threatening | False |
| Requires inpatient or prolongation of existing Hospitalization | False |
| Hospital Admission Date (dd MMM yyyy) | |
| Hospital Discharge Date (dd MMM yyyy) | |
| Admitted to ICU? | Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/> |
| Number of Days in ICU | |

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 29 Apr 2021 12:33:04

Generated On: 09 Jun 2021 16:57:13

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

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 29 Apr 2021 12:33:04

Generated On: 09 Jun 2021 16:57:13

| | |
|--|--|
| AEID | |
| Adverse event | HYPERLIPIDEMIA |
| 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) | 20 FEB 2021 |
| Start time (00:00-23:59) | |
| AE start date and time (derived) | |
| Ongoing? | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| If not Ongoing, end date (dd MMM yyyy) | |
| End time (00:00-23:59) | |
| AE End Date and Time (derived) | |
| Severity | Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/> |
| Is the adverse event serious? | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| AE is serious due To (check all that apply) | |
| Death | False |
| Life threatening | False |
| Requires inpatient or prolongation of existing Hospitalization | False |
| Hospital Admission Date (dd MMM yyyy) | |
| Hospital Discharge Date (dd MMM yyyy) | |
| Admitted to ICU? | Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/> |
| Number of Days in ICU | |

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 29 Apr 2021 12:33:04

Generated On: 09 Jun 2021 16:57:13

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

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 29 Apr 2021 12:33:04

Generated On: 09 Jun 2021 16:57:13

| | |
|--|--|
| AEID | |
| Adverse event | HYPERGLYCEMIA |
| 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) | 20 FEB 2021 |
| Start time (00:00-23:59) | |
| AE start date and time (derived) | |
| Ongoing? | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| If not Ongoing, end date (dd MMM yyyy) | |
| End time (00:00-23:59) | |
| AE End Date and Time (derived) | |
| Severity | Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/> |
| Is the adverse event serious? | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| AE is serious due To (check all that apply) | |
| Death | False |
| Life threatening | False |
| Requires inpatient or prolongation of existing Hospitalization | False |
| Hospital Admission Date (dd MMM yyyy) | |
| Hospital Discharge Date (dd MMM yyyy) | |
| Admitted to ICU? | Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/> |
| Number of Days in ICU | |

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 29 Apr 2021 12:33:04

Generated On: 09 Jun 2021 16:57:13

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

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Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 29 Apr 2021 12:33:04

Generated On: 09 Jun 2021 16:57:13

| | |
|--|--|
| AEID | |
| Adverse event | MILD MITRAL VALVE REGURGITATION |
| 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) | 20 FEB 2021 |
| Start time (00:00-23:59) | |
| AE start date and time (derived) | |
| Ongoing? | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| If not Ongoing, end date (dd MMM yyyy) | |
| End time (00:00-23:59) | |
| AE End Date and Time (derived) | |
| Severity | Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/> |
| Is the adverse event serious? | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| AE is serious due To (check all that apply) | |
| Death | False |
| Life threatening | False |
| Requires inpatient or prolongation of existing Hospitalization | False |
| Hospital Admission Date (dd MMM yyyy) | |
| Hospital Discharge Date (dd MMM yyyy) | |
| Admitted to ICU? | Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/> |

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Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 29 Apr 2021 12:33:04

Generated On: 09 Jun 2021 16:57:13

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

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Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 29 Apr 2021 12:33:04

Generated On: 09 Jun 2021 16:57:13

AEID

Adverse event

CHEST PRESSURE

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

19 FEB 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

19 FEB 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 29 Apr 2021 12:33:04

Generated On: 09 Jun 2021 16:57:13

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

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Folder: Adverse Events

Form: Adverse Events (9)

Data signed: (b) (4) 29 Apr 2021 12:33:04

Generated On: 09 Jun 2021 16:57:13

| | |
|--|--|
| AEID | |
| Adverse event | CORONARY ARTERY DISEASE (CAD; NON-OBSTRUCTIVE) |
| 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) | 19 FEB 2021 |
| Start time (00:00-23:59) | |
| AE start date and time (derived) | |
| Ongoing? | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| If not Ongoing, end date (dd MMM yyyy) | |
| End time (00:00-23:59) | |
| AE End Date and Time (derived) | |
| Severity | Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/> |
| Is the adverse event serious? | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| AE is serious due To (check all that apply) | |
| Death | False |
| Life threatening | False |
| Requires inpatient or prolongation of existing Hospitalization | False |
| Hospital Admission Date (dd MMM yyyy) | |
| Hospital Discharge Date (dd MMM yyyy) | |
| Admitted to ICU? | Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/> |

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Folder: Adverse Events

Form: Adverse Events (9)

Data signed: (b) (4) 29 Apr 2021 12:33:04

Generated On: 09 Jun 2021 16:57:13

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

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 19 Feb 2021 18:02:55

Generated On: 09 Jun 2021 16:57:13

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

Yes ☒

No ☐

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 20 Apr 2021 17:48:51

Generated On: 09 Jun 2021 16:57:13

Name of Medication TRIAMTERENE HCTZ

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 37.5/12.5

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 20 Apr 2021 17:48:51

Generated On: 09 Jun 2021 16:57:13

| | | |
|--|--------------------------|----------------------------------|
| | 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 2014 | |
| 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) 20 Apr 2021 17:48:51

Generated On: 09 Jun 2021 16:57:13

Name of Medication TYLENOL

Prophylaxis Yes ☐
No ☒

Indication ARTHRITIS

Dose per administration 325

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 20 Apr 2021 17:48:51

Generated On: 09 Jun 2021 16:57:13

| | | |
|--|--------------------------|----------------------------------|
| | 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 1990 | |
| 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 (3)

Data signed: (b) (4) 20 Apr 2021 17:48:51

Generated On: 09 Jun 2021 16:57:13

Name of Medication IBUPROFEN

Prophylaxis Yes ☐
No ☒

Indication ARTHRITIS

Dose per administration 200

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 20 Apr 2021 17:48:51

Generated On: 09 Jun 2021 16:57:13

| | | |
|--|--------------------------|----------------------------------|
| | 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 1990 | |
| 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 (4)

Data signed: (b) (4) 20 Apr 2021 17:48:51

Generated On: 09 Jun 2021 16:57:13

Name of Medication AUGMENTIN

Prophylaxis Yes ☐
No ☒

Indication TOOTH ABSCESS

Dose per administration 875/125

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 20 Apr 2021 17:48:51

Generated On: 09 Jun 2021 16:57:13

| | | |
|--|--------------------------|-------------------------------------|
| | 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) | 18 JAN 2021 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy) 19 JAN 2021 | | |
| Was this medication taken for solicited event? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| Separate Dosage Number (derived) | 2 | |
| Interval Dosage Unit Number (derived) | 1 | |
| Interval Dosage Definition (derived) | 802 | <input type="checkbox"/> |
| | 803 | <input type="checkbox"/> |
| | 804 | <input checked="" type="checkbox"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 20 Apr 2021 17:48:51

Generated On: 09 Jun 2021 16:57:13

Name of Medication ZITHROMAX

Prophylaxis Yes ☐
No ☒

Indication TOOTH ABSCESS

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 20 Apr 2021 17:48:51

Generated On: 09 Jun 2021 16:57:13

| | | |
|--|--------------------------------------|--------------------------|
| | Intramuscular | <input type="checkbox"/> |
| | Respiratory (Inhalation) | <input type="checkbox"/> |
| | Intralesional | <input type="checkbox"/> |
| | Intraperitoneal | <input type="checkbox"/> |
| | Nasal | <input type="checkbox"/> |
| | Vaginal | <input type="checkbox"/> |
| | Rectal | <input type="checkbox"/> |
| | Intravenous | <input type="checkbox"/> |
| | Intravenous Bolus | <input type="checkbox"/> |
| | Intravenous Drip | <input type="checkbox"/> |
| | Other | <input type="checkbox"/> |
| If route of administration is Other, specify _____ | | |
| Start date (dd MMM yyyy) | 19 JAN 2021 | |
| Start date completely unknown | False | |
| Ongoing? | Yes <input type="checkbox"/> | |
| | No <input checked="" type="radio"/> | |
| If not Ongoing, End date (dd MMM yyyy) 19 JAN 2021 | | |
| Was this medication taken for solicited event? | Yes <input type="checkbox"/> | |
| | No <input checked="" type="radio"/> | |
| Separate Dosage Number (derived) | 1 | |
| Interval Dosage Unit Number (derived) | 1 | |
| Interval Dosage Definition (derived) | 802 <input type="checkbox"/> | |
| | 803 <input type="checkbox"/> | |
| | 804 <input checked="" type="radio"/> | |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 20 Apr 2021 17:48:51

Generated On: 09 Jun 2021 16:57:13

Name of Medication ZITHROMAX

Prophylaxis Yes ☐
No ☒

Indication TOOTH ABCESS

Dose per administration 250

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 20 Apr 2021 17:48:51

Generated On: 09 Jun 2021 16:57:13

| | | |
|--|--------------------------|-------------------------------------|
| | Intramuscular | <input type="checkbox"/> |
| | Respiratory (Inhalation) | <input type="checkbox"/> |
| | Intralesional | <input type="checkbox"/> |
| | Intraperitoneal | <input type="checkbox"/> |
| | Nasal | <input type="checkbox"/> |
| | Vaginal | <input type="checkbox"/> |
| | Rectal | <input type="checkbox"/> |
| | Intravenous | <input type="checkbox"/> |
| | Intravenous Bolus | <input type="checkbox"/> |
| | Intravenous Drip | <input type="checkbox"/> |
| | Other | <input type="checkbox"/> |
| If route of administration is Other, specify _____ | | |
| Start date (dd MMM yyyy) | 20 JAN 2021 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy) | | 30 JAN 2021 |
| 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"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 20 Apr 2021 17:48:51

Generated On: 09 Jun 2021 16:57:13

Name of Medication VITAMIN D
(CHOLECALCIFEROL)

Prophylaxis Yes ☐
No ☒

Indication CORONARY ARTERY DISEASE

Dose per administration 4,000

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 20 Apr 2021 17:48:51

Generated On: 09 Jun 2021 16:57:13

| | | |
|--|--------------------------|----------------------------------|
| | Intraocular | <input type="checkbox"/> |
| | Intramuscular | <input type="checkbox"/> |
| | Respiratory (Inhalation) | <input type="checkbox"/> |
| | Intralesional | <input type="checkbox"/> |
| | Intraperitoneal | <input type="checkbox"/> |
| | Nasal | <input type="checkbox"/> |
| | Vaginal | <input type="checkbox"/> |
| | Rectal | <input type="checkbox"/> |
| | Intravenous | <input type="checkbox"/> |
| | Intravenous Bolus | <input type="checkbox"/> |
| | Intravenous Drip | <input type="checkbox"/> |
| | Other | <input type="checkbox"/> |
| If route of administration is Other, specify _____ | | |
| Start date (dd MMM yyyy) | | 19 FEB 2021 |
| Start date completely unknown | | False |
| Ongoing? | Yes | <input checked="" type="radio"/> |
| | No | <input type="radio"/> |
| If not Ongoing, End date (dd MMM yyyy) _____ | | |
| Was this medication taken for solicited event? | Yes | <input type="radio"/> |
| | No | <input checked="" type="radio"/> |
| Separate Dosage Number (derived) | | 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 (8)

Data signed: (b) (4) 20 Apr 2021 17:48:51

Generated On: 09 Jun 2021 16:57:13

Name of Medication CARVEDILOL

Prophylaxis Yes ☐
No ☒

Indication CONGESTIVE HEART FAILURE
(AE)

Dose per administration 6.25

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

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| | | |
|--|--------------------------|----------------------------------|
| | Intraocular | <input type="checkbox"/> |
| | Intramuscular | <input type="checkbox"/> |
| | Respiratory (Inhalation) | <input type="checkbox"/> |
| | Intralesional | <input type="checkbox"/> |
| | Intraperitoneal | <input type="checkbox"/> |
| | Nasal | <input type="checkbox"/> |
| | Vaginal | <input type="checkbox"/> |
| | Rectal | <input type="checkbox"/> |
| | Intravenous | <input type="checkbox"/> |
| | Intravenous Bolus | <input type="checkbox"/> |
| | Intravenous Drip | <input type="checkbox"/> |
| | Other | <input type="checkbox"/> |
| If route of administration is Other, specify _____ | | |
| Start date (dd MMM yyyy) | | 19 FEB 2021 |
| Start date completely unknown | | False |
| Ongoing? | Yes | <input checked="" type="radio"/> |
| | No | <input type="radio"/> |
| If not Ongoing, End date (dd MMM yyyy) _____ | | |
| Was this medication taken for solicited event? | Yes | <input type="radio"/> |
| | No | <input checked="" type="radio"/> |
| Separate Dosage Number (derived) | | 2 |
| 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 (9)

Data signed: (b) (4) 20 Apr 2021 17:48:51

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Name of Medication LOVENOX

Prophylaxis Yes ☒
No ☐

Indication DVT PROPHYLAXIS

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 20 Apr 2021 17:48:51

Generated On: 09 Jun 2021 16:57:13

| | | |
|--|--------------------------|-------------------------------------|
| | Intramuscular | <input type="checkbox"/> |
| | Respiratory (Inhalation) | <input type="checkbox"/> |
| | Intralesional | <input type="checkbox"/> |
| | Intraperitoneal | <input type="checkbox"/> |
| | Nasal | <input type="checkbox"/> |
| | Vaginal | <input type="checkbox"/> |
| | Rectal | <input type="checkbox"/> |
| | Intravenous | <input type="checkbox"/> |
| | Intravenous Bolus | <input type="checkbox"/> |
| | Intravenous Drip | <input type="checkbox"/> |
| | Other | <input type="checkbox"/> |
| If route of administration is Other, specify _____ | | |
| Start date (dd MMM yyyy) | | 19 FEB 2021 |
| Start date completely unknown | | False |
| Ongoing? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy) | | 22 FEB 2021 |
| 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"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 20 Apr 2021 17:48:51

Generated On: 09 Jun 2021 16:57:13

Name of Medication ATROVASTATIN

Prophylaxis Yes ☐
No ☒

Indication HYPERLIPIDEMIA

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 20 Apr 2021 17:48:51

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| | | |
|--|--------------------------|----------------------------------|
| | Intramuscular | <input type="checkbox"/> |
| | Respiratory (Inhalation) | <input type="checkbox"/> |
| | Intralesional | <input type="checkbox"/> |
| | Intraperitoneal | <input type="checkbox"/> |
| | Nasal | <input type="checkbox"/> |
| | Vaginal | <input type="checkbox"/> |
| | Rectal | <input type="checkbox"/> |
| | Intravenous | <input type="checkbox"/> |
| | Intravenous Bolus | <input type="checkbox"/> |
| | Intravenous Drip | <input type="checkbox"/> |
| | Other | <input type="checkbox"/> |
| If route of administration is Other, specify _____ | | |
| Start date (dd MMM yyyy) | 19 FEB 2021 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input checked="" type="radio"/> |
| | No | <input type="radio"/> |
| If not Ongoing, End date (dd MMM yyyy) _____ | | |
| Was this medication taken for solicited event? | Yes | <input type="radio"/> |
| | No | <input checked="" type="radio"/> |
| Separate Dosage Number (derived) | 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 (11)

Data signed: (b) (4) 20 Apr 2021 17:48:51

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Name of Medication CLOPIDOGREL/ ASPIRIN

Prophylaxis Yes ☐
No ☒

Indication CORONARY ARTERY DISEASE
(CAD)

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 20 Apr 2021 17:48:51

Generated On: 09 Jun 2021 16:57:13

| | | |
|--|--------------------------|-------------------------------------|
| | Intraocular | <input type="checkbox"/> |
| | Intramuscular | <input type="checkbox"/> |
| | Respiratory (Inhalation) | <input type="checkbox"/> |
| | Intralesional | <input type="checkbox"/> |
| | Intraperitoneal | <input type="checkbox"/> |
| | Nasal | <input type="checkbox"/> |
| | Vaginal | <input type="checkbox"/> |
| | Rectal | <input type="checkbox"/> |
| | Intravenous | <input type="checkbox"/> |
| | Intravenous Bolus | <input type="checkbox"/> |
| | Intravenous Drip | <input type="checkbox"/> |
| | Other | <input type="checkbox"/> |
| If route of administration is Other, specify | | |
| Start date (dd MMM yyyy) | 19 FEB 2021 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy) | | 19 FEB 2021 |
| 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"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 20 Apr 2021 17:48:51

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Name of Medication SOLU-CORTEF

Prophylaxis Yes ☐
No ☒

Indication HEART CATH

Dose per administration 200

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 20 Apr 2021 17:48:51

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| | | |
|--|-------------------------------------|----------------------------------|
| | 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 checked="" 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) | 20 FEB 2021 | |
| Start date completely unknown | False | |
| Ongoing? | Yes <input type="radio"/> | |
| | No <input checked="" type="radio"/> | |
| If not Ongoing, End date (dd MMM yyyy) | 20 FEB 2021 | |
| 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 (13)

Data signed: (b) (4) 20 Apr 2021 17:48:51

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Name of Medication BENADRYL

Prophylaxis Yes ☐
No ☒

Indication HEART CATH

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 20 Apr 2021 17:48:51

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| | | |
|--|-------------------------------------|----------------------------------|
| | 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 checked="" 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) | 20 FEB 2021 | |
| Start date completely unknown | False | |
| Ongoing? | Yes <input type="radio"/> | |
| | No <input checked="" type="radio"/> | |
| If not Ongoing, End date (dd MMM yyyy) | | 20 FEB 2021 |
| 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 (14)

Data signed: (b) (4) 20 Apr 2021 17:48:51

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Name of Medication FENTANYL

Prophylaxis Yes ☐
No ☒

Indication HEART CATH

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 20 Apr 2021 17:48:51

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| | | |
|--|--------------------------|-------------------------------------|
| | Intramuscular | <input type="checkbox"/> |
| | Respiratory (Inhalation) | <input type="checkbox"/> |
| | Intralesional | <input type="checkbox"/> |
| | Intraperitoneal | <input type="checkbox"/> |
| | Nasal | <input type="checkbox"/> |
| | Vaginal | <input type="checkbox"/> |
| | Rectal | <input type="checkbox"/> |
| | Intravenous | <input checked="" type="checkbox"/> |
| | Intravenous Bolus | <input type="checkbox"/> |
| | Intravenous Drip | <input type="checkbox"/> |
| | Other | <input type="checkbox"/> |
| If route of administration is Other, specify _____ | | |
| Start date (dd MMM yyyy) | | 20 FEB 2021 |
| Start date completely unknown | | False |
| Ongoing? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy) | | 20 FEB 2021 |
| Was this medication taken for solicited event? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| Separate Dosage Number (derived) _____ | | |
| Interval Dosage Unit Number (derived) _____ | | |
| Interval Dosage Definition (derived) | 802 | <input type="checkbox"/> |
| | 803 | <input type="checkbox"/> |
| | 804 | <input type="checkbox"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 20 Apr 2021 17:48:51

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Name of Medication VERSED

Prophylaxis Yes ☐

No ☒

Indication HEART CATH

Dose per administration 2

Dose unit mg ☒

ug ☐

mL ☐

g ☐

IU ☐

tablet ☐

capsule ☐

puff ☐

Other ☐

If dose unit is Other, specify

Frequency once daily ☐

twice daily ☐

three times daily ☐

four times daily ☐

every other day ☐

every week ☐

every month ☐

as needed ☐

once ☒

unknown ☐

other ☐

If frequency is Other, specify

Route of administration Oral ☐

Topical ☐

Subcutaneous ☐

Transdermal ☐

Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 20 Apr 2021 17:48:51

Generated On: 09 Jun 2021 16:57:13

| | | |
|--|--------------------------|----------------------------------|
| | 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 checked="" 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) | 20 FEB 2021 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input type="radio"/> |
| | No | <input checked="" type="radio"/> |
| If not Ongoing, End date (dd MMM yyyy) | | 20 FEB 2021 |
| 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 (16)

Data signed: (b) (4) 20 Apr 2021 17:48:51

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Name of Medication LIDOCAINE

Prophylaxis Yes ☐
No ☒

Indication HEART CATH

Dose per administration 1

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

If dose unit is Other, specify PERCENT (%)

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 20 Apr 2021 17:48:51

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| | | |
|--|--------------------------|----------------------------------|
| | 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 checked="" type="radio"/> |
| If route of administration is Other, specify | | LOCAL INJECTION |
| Start date (dd MMM yyyy) | 20 FEB 2021 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input type="radio"/> |
| | No | <input checked="" type="radio"/> |
| If not Ongoing, End date (dd MMM yyyy) | | 20 FEB 2021 |
| 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 (17)

Data signed: (b) (4) 20 Apr 2021 17:48:51

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Name of Medication LIPITOR

Prophylaxis Yes ☐
No ☒

Indication HYPERLIPIDEMIA

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Form: Prior/Concomitant Medication and Vaccination (17)

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| | | |
|--|--------------------------|----------------------------------|
| | Intramuscular | <input type="checkbox"/> |
| | Respiratory (Inhalation) | <input type="checkbox"/> |
| | Intralesional | <input type="checkbox"/> |
| | Intraperitoneal | <input type="checkbox"/> |
| | Nasal | <input type="checkbox"/> |
| | Vaginal | <input type="checkbox"/> |
| | Rectal | <input type="checkbox"/> |
| | Intravenous | <input type="checkbox"/> |
| | Intravenous Bolus | <input type="checkbox"/> |
| | Intravenous Drip | <input type="checkbox"/> |
| | Other | <input type="checkbox"/> |
| If route of administration is Other, specify _____ | | |
| Start date (dd MMM yyyy) | | 23 FEB 2021 |
| Start date completely unknown | | False |
| Ongoing? | Yes | <input checked="" type="radio"/> |
| | No | <input type="radio"/> |
| If not Ongoing, End date (dd MMM yyyy) _____ | | |
| Was this medication taken for solicited event? | Yes | <input type="radio"/> |
| | No | <input checked="" type="radio"/> |
| Separate Dosage Number (derived) | | 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 (18)

Data signed: (b) (4) 20 Apr 2021 17:48:51

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Name of Medication CARVEDILOL

Prophylaxis Yes ☐
No ☒

Indication CONGESTIVE HEART FAILURE
(CHF)

Dose per administration 12.5

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 20 Apr 2021 17:48:51

Generated On: 09 Jun 2021 16:57:13

| | | |
|--|--------------------------|----------------------------------|
| | Intraocular | <input type="checkbox"/> |
| | Intramuscular | <input type="checkbox"/> |
| | Respiratory (Inhalation) | <input type="checkbox"/> |
| | Intralesional | <input type="checkbox"/> |
| | Intraperitoneal | <input type="checkbox"/> |
| | Nasal | <input type="checkbox"/> |
| | Vaginal | <input type="checkbox"/> |
| | Rectal | <input type="checkbox"/> |
| | Intravenous | <input type="checkbox"/> |
| | Intravenous Bolus | <input type="checkbox"/> |
| | Intravenous Drip | <input type="checkbox"/> |
| | Other | <input type="checkbox"/> |
| If route of administration is Other, specify _____ | | |
| Start date (dd MMM yyyy) | | 23 FEB 2021 |
| Start date completely unknown | | False |
| Ongoing? | Yes | <input checked="" type="radio"/> |
| | No | <input type="radio"/> |
| If not Ongoing, End date (dd MMM yyyy) _____ | | |
| Was this medication taken for solicited event? | Yes | <input type="radio"/> |
| | No | <input checked="" type="radio"/> |
| Separate Dosage Number (derived) | | 2 |
| Interval Dosage Unit Number (derived) | | 1 |
| Interval Dosage Definition (derived) | 802 | <input type="radio"/> |
| | 803 | <input type="radio"/> |
| | 804 | <input checked="" type="radio"/> |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 20 Apr 2021 17:48:51

Generated On: 09 Jun 2021 16:57:13

Name of Medication ASPIRIN

Prophylaxis Yes ☐
No ☒

Indication CORONARY ARTERY DISEASE
(CAD)

Dose per administration 81

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

385 of 2565

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 20 Apr 2021 17:48:51

Generated On: 09 Jun 2021 16:57:13

| | | |
|--|--------------------------|----------------------------------|
| | Intraocular | <input type="checkbox"/> |
| | Intramuscular | <input type="checkbox"/> |
| | Respiratory (Inhalation) | <input type="checkbox"/> |
| | Intralesional | <input type="checkbox"/> |
| | Intraperitoneal | <input type="checkbox"/> |
| | Nasal | <input type="checkbox"/> |
| | Vaginal | <input type="checkbox"/> |
| | Rectal | <input type="checkbox"/> |
| | Intravenous | <input type="checkbox"/> |
| | Intravenous Bolus | <input type="checkbox"/> |
| | Intravenous Drip | <input type="checkbox"/> |
| | Other | <input type="checkbox"/> |
| If route of administration is Other, specify _____ | | |
| Start date (dd MMM yyyy) | | 23 FEB 2021 |
| Start date completely unknown | | False |
| Ongoing? | Yes | <input checked="" type="radio"/> |
| | No | <input type="radio"/> |
| If not Ongoing, End date (dd MMM yyyy) _____ | | |
| Was this medication taken for solicited event? | Yes | <input type="radio"/> |
| | No | <input checked="" type="radio"/> |
| Separate Dosage Number (derived) | | 1 |
| Interval Dosage Unit Number (derived) | | 1 |
| Interval Dosage Definition (derived) | 802 | <input type="radio"/> |
| | 803 | <input type="radio"/> |
| | 804 | <input checked="" type="radio"/> |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 20 Apr 2021 17:48:51

Generated On: 09 Jun 2021 16:57:13

Name of Medication CLOPIDOGREL

Prophylaxis Yes ☐
No ☒

Indication CORONARY ARTERY DISEASE
(CAD)

Dose per administration 75

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 20 Apr 2021 17:48:51

Generated On: 09 Jun 2021 16:57:13

| | | |
|--|--------------------------|----------------------------------|
| | Intraocular | <input type="checkbox"/> |
| | Intramuscular | <input type="checkbox"/> |
| | Respiratory (Inhalation) | <input type="checkbox"/> |
| | Intralesional | <input type="checkbox"/> |
| | Intraperitoneal | <input type="checkbox"/> |
| | Nasal | <input type="checkbox"/> |
| | Vaginal | <input type="checkbox"/> |
| | Rectal | <input type="checkbox"/> |
| | Intravenous | <input type="checkbox"/> |
| | Intravenous Bolus | <input type="checkbox"/> |
| | Intravenous Drip | <input type="checkbox"/> |
| | Other | <input type="checkbox"/> |
| If route of administration is Other, specify _____ | | |
| Start date (dd MMM yyyy) | | 23 FEB 2021 |
| Start date completely unknown | | False |
| Ongoing? | Yes | <input checked="" type="radio"/> |
| | No | <input type="radio"/> |
| If not Ongoing, End date (dd MMM yyyy) _____ | | |
| Was this medication taken for solicited event? | Yes | <input type="radio"/> |
| | No | <input checked="" type="radio"/> |
| Separate Dosage Number (derived) | | 1 |
| Interval Dosage Unit Number (derived) | | 1 |
| Interval Dosage Definition (derived) | 802 | <input type="radio"/> |
| | 803 | <input type="radio"/> |
| | 804 | <input checked="" type="radio"/> |

US3302105

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 09 Apr 2021 12:37:50

Generated On: 09 Jun 2021 16:57:13

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3302105

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 09 Apr 2021 12:37:50

Generated On: 09 Jun 2021 16:57:13

| Procedure/Surgery date (dd MMM yyyy) | Procedure/Surgery | Indication | If indication is Other, specify |
|---|-------------------|------------|---------------------------------|
| 20 FEB 2021 | HEART CATH | Other | MYOCARDIAL INFARCTION (SAE) |

US3302105

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 16:57:13

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

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

US3302105

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 16:57:13

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 ☐

US3302105

Folder: SAE USA-US087-2021-MRNA-1273-P301000020

Form: Safety Report Form

Data signed: (b) (4) 20 Apr 2021 17:48:52

Generated On: 09 Jun 2021 16:57:13

| | |
|--|--|
| SAEID | USA-US087-2021-MRNA-1273-P301000020 |
| Serious | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Death | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Life threatening | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Requires inpatient or prolongation of existing Hospitalization | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Persistent or significant disability or incapacity | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Congenital anomaly or birth defect | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Other medically important event | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Investigator's First Name | GREGORY |
| Investigator's Last Name | FELDMAN |
| Site Address: Street | 141 HAROLD FLEMING COURT |
| Site Address: City | SPARTANBURG |
| Site Address: State | |
| Site Address: Postal Code | 29303 |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 7 |

US3302105

Folder: SAE USA-US087-2021-MRNA-1273-P301000020

Form: Safety Report Form (1)

Data signed: (b) (4) 20 Apr 2021 17:48:52

Generated On: 09 Jun 2021 16:57:13

| | |
|---|--|
| SAEID | USA-US087-2021-MRNA-1273-P301000020 |
| Serious | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Death | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Life threatening | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Requires inpatient or prolongation of existing Hospitalization | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Persistent or significant disability or incapacity | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Congenital anomaly or birth defect | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Other medically important event | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Investigator's First Name | GREGORY |
| Investigator's Last Name | FELDMAN |
| Site Address: Street | 141 HAROLD FLEMING COURT |
| Site Address: City | SPARTANBURG |
| Site Address: State | |
| Site Address: Postal Code | 29303 |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 7 |
| Date of submission (Pre-filled from custom function) | 22/FEB/2021 14:18 |
| Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge. | True |

US3302105

Folder: SAE USA-US087-2021-MRNA-1273-P301000020

Form: Safety Report Form (2)

Data signed: (b) (4) 20 Apr 2021 17:48:52

Generated On: 09 Jun 2021 16:57:13

| | |
|---|--|
| SAEID | USA-US087-2021-MRNA-1273-P301000020 |
| Serious | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Death | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Life threatening | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Requires inpatient or prolongation of existing Hospitalization | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Persistent or significant disability or incapacity | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Congenital anomaly or birth defect | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Other medically important event | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Investigator's First Name | GREGORY |
| Investigator's Last Name | FELDMAN |
| Site Address: Street | 141 HAROLD FLEMING COURT |
| Site Address: City | SPARTANBURG |
| Site Address: State | |
| Site Address: Postal Code | 29303 |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 7 |
| Date of submission (Pre-filled from custom function) | 08/MAR/2021 16:21 |
| Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge. | True |

US3302105

Folder: SAE USA-US087-2021-MRNA-1273-P301000020

Form: Safety Report Form (3)

Data signed: (b) (4) 20 Apr 2021 17:48:52

Generated On: 09 Jun 2021 16:57:13

| | |
|---|--|
| SAEID | USA-US087-2021-MRNA-1273-P301000020 |
| Serious | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Death | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Life threatening | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Requires inpatient or prolongation of existing Hospitalization | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Persistent or significant disability or incapacity | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Congenital anomaly or birth defect | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Other medically important event | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Investigator's First Name | GREGORY |
| Investigator's Last Name | FELDMAN |
| Site Address: Street | 141 HAROLD FLEMING COURT |
| Site Address: City | SPARTANBURG |
| Site Address: State | |
| Site Address: Postal Code | 29303 |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 7 |
| Date of submission (Pre-filled from custom function) | 16/MAR/2021 10:28 |
| Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge. | True |

US3302105

Folder: SAE USA-US087-2021-MRNA-1273-P301000020

Form: Safety Report Form (4)

Data signed: (b) (4) 20 Apr 2021 17:48:52

Generated On: 09 Jun 2021 16:57:13

| | |
|---|--|
| SAEID | USA-US087-2021-MRNA-1273-P301000020 |
| Serious | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Death | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Life threatening | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Requires inpatient or prolongation of existing Hospitalization | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Persistent or significant disability or incapacity | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Congenital anomaly or birth defect | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Other medically important event | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Investigator's First Name | GREGORY |
| Investigator's Last Name | FELDMAN |
| Site Address: Street | 141 HAROLD FLEMING COURT |
| Site Address: City | SPARTANBURG |
| Site Address: State | |
| Site Address: Postal Code | 29303 |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 7 |
| Date of submission (Pre-filled from custom function) | 06/APR/2021 10:50 |
| Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge. | True |

US3302105

Folder: SAE USA-US087-2021-MRNA-1273-P301000020

Form: Safety Report Form (5)

Data signed: (b) (4) 20 Apr 2021 17:48:52

Generated On: 09 Jun 2021 16:57:13

| | |
|---|--|
| SAEID | USA-US087-2021-MRNA-1273-P301000020 |
| Serious | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Death | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Life threatening | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Requires inpatient or prolongation of existing Hospitalization | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Persistent or significant disability or incapacity | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Congenital anomaly or birth defect | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Other medically important event | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Investigator's First Name | GREGORY |
| Investigator's Last Name | FELDMAN |
| Site Address: Street | 141 HAROLD FLEMING COURT |
| Site Address: City | SPARTANBURG |
| Site Address: State | |
| Site Address: Postal Code | 29303 |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 7 |
| Date of submission (Pre-filled from custom function) | 07/APR/2021 08:52 |
| Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge. | True |

US3302105

Folder: SAE USA-US087-2021-MRNA-1273-P301000020

Form: Safety Report Form (6)

Data signed: (b) (4) 20 Apr 2021 17:48:52

Generated On: 09 Jun 2021 16:57:13

| | |
|---|--|
| SAEID | USA-US087-2021-MRNA-1273-P301000020 |
| Serious | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Death | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Life threatening | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Requires inpatient or prolongation of existing Hospitalization | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Persistent or significant disability or incapacity | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Congenital anomaly or birth defect | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Other medically important event | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Investigator's First Name | GREGORY |
| Investigator's Last Name | FELDMAN |
| Site Address: Street | 141 HAROLD FLEMING COURT |
| Site Address: City | SPARTANBURG |
| Site Address: State | |
| Site Address: Postal Code | 29303 |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 7 |
| Date of submission (Pre-filled from custom function) | 07/APR/2021 09:07 |
| Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge. | True |

US3302105

Folder: SAE USA-US087-2021-MRNA-1273-P301000020

Form: Safety Report Form (7)

Data signed: (b) (4) 20 Apr 2021 17:48:52

Generated On: 09 Jun 2021 16:57:13

| | |
|---|--|
| SAEID | USA-US087-2021-MRNA-1273-P301000020 |
| Serious | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Death | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Life threatening | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Requires inpatient or prolongation of existing Hospitalization | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Persistent or significant disability or incapacity | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Congenital anomaly or birth defect | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Other medically important event | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Investigator's First Name | GREGORY |
| Investigator's Last Name | FELDMAN |
| Site Address: Street | 141 HAROLD FLEMING COURT |
| Site Address: City | SPARTANBURG |
| Site Address: State | |
| Site Address: Postal Code | 29303 |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 7 |
| Date of submission (Pre-filled from custom function) | 14/APR/2021 07:46 |
| Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge. | True |

Audit

US3302105 (Prod: Keystone VitaLink Research - Spartanburg - PPDS)

US3302105

Form: Participant Creation

Generated On: 09 Jun 2021 16:57:13

[Participant ID](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:02:55 |
| User entered 'US3302105' | (b) (4) RWS_ENDPOINT ENDPOINT (b) (4) | 07 Aug 2020 19:39:18 |

US3302105

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:57:13

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 09:16:21 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:03:00 |
| User entered 'Yes (Y)' | (b) (4) Brittany Belcher (b) (4) | 07 Aug 2020 20:05:29 |

US3302105

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:57:13

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

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 09:16:21 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:03:00 |
| User entered '07 AUG 2020' | (b) (4) RWS_ENDPOINT ENDPOINT (b) (4) | 07 Aug 2020 19:39:19 |

US3302105

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:57:13

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

| Audit | User | Time (GMT) |
|--------------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 09:16:21 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:03:00 |
| User entered 'Clinic (Clinic)' | (b) (4) Brittany Belcher (b) (4) | 07 Aug 2020 20:05:29 |

US3302105

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:57:13

[Folder OID](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 09:16:21 |
| User entered 'SCRN' | System | 07 Aug 2020 20:05:29 |

US3302105

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:57:13

Date of Birth (MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 09:16:21 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:03:00 |
| User entered (b) (6) 1949' | (b) (4) RWS_ENDPOINT ENDPOINT (b) (4) | 07 Aug 2020 19:39:20 |

US3302105

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:57:13

[Age](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 09:16:21 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:03:00 |
| User entered '71' | (b) (4) Brittany Belcher (b) (4) | 07 Aug 2020 20:06:30 |

US3302105

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:57:13

[Age Units](#)

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 09:16:21 |
| User entered 'YEARS' | System | 07 Aug 2020 20:06:30 |

US3302105

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:57:13

[Age \(Derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 09:16:21 |
| User entered '71' | System | 07 Aug 2020 20:06:40 |

US3302105

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:57:13

Sex

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 09:16:21 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:03:00 |
| User entered 'Female (F)' | (b) (4) Brittany Belcher (b) (4) | 07 Aug 2020 20:06:30 |

US3302105

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:57:13

[Ethnicity](#)

| Audit | User | Time (GMT) |
|--|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 09:16:21 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:03:00 |
| User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)' | (b) (4) Brittany Belcher (b) (4) | 07 Aug 2020 20:06:30 |

US3302105

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:57:13

[White](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 09:16:21 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:03:00 |
| User entered 'I' | (b) (4) Brittany Belcher (b) (4) | 07 Aug 2020 20:06:30 |

US3302105

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:57:13

[Black](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 09:16:21 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:03:00 |
| User entered '0' | (b) (4) Brittany Belcher (b) (4) | 07 Aug 2020 20:06:30 |

US3302105

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:57:13

[Asian](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 09:16:21 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:03:00 |
| User entered '0' | (b) (4) Brittany Belcher (b) (4) | 07 Aug 2020 20:06:30 |

US3302105

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:57:13

[American Indian or Alaska Native](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 09:16:21 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:03:00 |
| User entered '0' | (b) (4) Brittany Belcher (b) (4) | 07 Aug 2020 20:06:30 |

US3302105

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:57:13

[Native Hawaiian or other Pacific Islander](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 09:16:21 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:03:00 |
| User entered '0' | (b) (4) Brittany Belcher (b) (4) | 07 Aug 2020 20:06:30 |

US3302105

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:57:13

[Other](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 09:16:21 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:03:00 |
| User entered '0' | (b) (4) Brittany Belcher (b) (4) | 07 Aug 2020 20:06:30 |

US3302105

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:57:13

If race is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 09:16:21 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:03:00 |
| User entered empty. | (b) (4) | 07 Aug 2020 20:06:30 |

US3302105

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:57:13

[Unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 09:16:21 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:03:00 |
| User entered '0' | (b) (4) Brittany Belcher (b) (4) | 07 Aug 2020 20:06:30 |

US3302105

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:57:13

[Not reported](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 09:16:21 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:03:00 |
| User entered '0' | (b) (4) Brittany Belcher (b) (4) | 07 Aug 2020 20:06:30 |

US3302105

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:57:13

Date of Informed Consent (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 09:16:21 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:03:00 |
| User entered '07 Aug 2020' reason for change: Data Entry Error | (b) (4) | |
| | Brittany Belcher (b) (4) | 04 Nov 2020 18:22:09 |
| User entered '7 Aug 2020' | (b) (4) | |
| | Brittany Belcher (b) (4) | 07 Aug 2020 20:06:40 |

US3302105

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:57:13

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 09:16:21 |
| User entered 'Aug 2020' | System | 07 Aug 2020 20:06:40 |

US3302105

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:57:13

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 09:16:21 |
| User entered '2020' | System | 07 Aug 2020 20:06:40 |

US3302105

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:57:13

[Protocol Version](#)

| Audit | User | Time (GMT) |
|--------------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 09:16:21 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:03:00 |
| User entered 'Amendment 1 (1)' | (b) (4) Brittany Belcher (b) (4) | 07 Aug 2020 20:06:40 |

US3302105

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:57:13

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

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 09:16:21 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:03:00 |
| User entered 'Yes (Y)' | (b) (4) Brittany Belcher (b) (4) | 07 Aug 2020 20:06:40 |

US3302105

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:57:13

If No, indicate reason for screen fail

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 09:16:21 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:03:00 |
| User entered empty. | (b) (4) | 07 Aug 2020 20:06:40 |

US3302105

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:57:13

If reason for screen fail is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 09:16:21 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:03:00 |
| User entered empty. | (b) (4) Brittany Belcher (b) (4) | 07 Aug 2020 20:06:40 |

US3302105

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:57:13

[Was this participant screened previously?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 09:16:21 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:03:00 |
| User entered 'No (N)' | (b) (4) Brittany Belcher (b) (4) | 07 Aug 2020 20:06:40 |

US3302105

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:57:13

[If Yes, previous participant number](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 09:16:21 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:03:00 |
| User entered empty. | (b) (4) RWS_ENDPOINT ENDPOINT (b) (4) | 07 Aug 2020 19:39:19 |

US3302105

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:57:13

[Enrollment Trigger](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 09:16:21 |
| User entered 'I' | System | 07 Aug 2020 20:06:44 |

US3302105

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 16:57:13

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

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 09:16:21 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:03:00 |
| User entered 'Yes (Y)' | (b) (4) Brittany Belcher (b) (4) | 07 Aug 2020 20:06:44 |

US3302105

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 16:57:13

[Were any significant conditions reported?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 09:16:21 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:03:00 |
| User entered 'Yes (Y)' | (b) (4) Brittany Belcher (b) (4) | 07 Aug 2020 20:07:14 |

US3302105

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:57:13

Condition

| Audit | User | Time (GMT) |
|---|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 09:16:21 |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| Signature has been broken. | Brittany Belcher (b) (4) | 05 Apr 2021 14:29:46 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:03:00 |
| User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0. | Coder Import (b) (4) | 07 Aug 2020 20:10:19 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 07 Aug 2020 20:10:19 |
| Data point term sent to Coder | System | 07 Aug 2020 20:08:30 |
| User entered 'hypertension' | Brittany Belcher (b) (4) | 07 Aug 2020 20:07:32 |

US3302105

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:57:13

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

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 09:16:21 |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| Signature has been broken. | (b) (4) Brittany Belcher (b) (4) | 05 Apr 2021 14:29:36 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:03:00 |
| User entered 'un UNK 2014' | (b) (4) Brittany Belcher (b) (4) | 07 Aug 2020 20:07:32 |

US3302105

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:57:13

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 09:16:21 |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| Signature has been broken. | (b) (4) Brittany Belcher (b) (4) | 05 Apr 2021 14:29:41 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:03:00 |
| User entered '0' | (b) (4) Brittany Belcher (b) (4) | 07 Aug 2020 20:07:32 |

US3302105

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:57:13

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 09:16:21 |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| Signature has been broken. | (b) (4) Brittany Belcher (b) (4) | 05 Apr 2021 14:29:52 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:03:00 |
| User entered 'Yes (Y)' | (b) (4) Brittany Belcher (b) (4) | 07 Aug 2020 20:07:32 |

US3302105

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:57:13

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

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 09:16:21 |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| Signature has been broken. | (b) (4) Brittany Belcher (b) (4) | 05 Apr 2021 14:29:23 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:03:00 |
| User entered empty. | (b) (4) Brittany Belcher (b) (4) | 07 Aug 2020 20:07:32 |

US3302105

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:57:13

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 09:16:21 |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| Signature has been broken. | (b) (4) Brittany Belcher (b) (4) | 05 Apr 2021 14:29:29 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:03:00 |
| User entered '0' | (b) (4) Brittany Belcher (b) (4) | 07 Aug 2020 20:07:32 |

US3302105

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:57:13

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 09:16:21 |
| User entered 'Jan 2014' | System | 07 Aug 2020 20:07:32 |

US3302105

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:57:13

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 09:16:21 |
| User entered '2014' | System | 07 Aug 2020 20:07:32 |

US3302105

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:57:13

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 09:16:21 |
| User entered empty. | System | 07 Aug 2020 20:07:32 |

US3302105

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:57:13

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 09:16:21 |
| User entered empty. | System | 07 Aug 2020 20:07:32 |

US3302105

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:57:13

Condition

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 09:16:21 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:03:00 |
| User closed query 'Per DM CLR: Please specify the type of ARTHRITIS (Rheumatoid versus Osteoarthritis) and the location. 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) (4), (b) (6) | 14 Oct 2020 06:59:23 |
| Query 'Per DM CLR: Please specify the type of ARTHRITIS (Rheumatoid versus Osteoarthritis) and the location. 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 'this is unspecified ' (Site from DM). | Brittany Belcher (b) (4) | 13 Oct 2020 20:54:22 |
| User opened query 'Per DM CLR: Please specify the type of ARTHRITIS (Rheumatoid versus Osteoarthritis) and the location. 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) | 21 Sep 2020 16:47:26 |
| User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Arthropathies NEC, PT: Arthritis, LLT: Arthritis - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 07 Aug 2020 20:10:19 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 07 Aug 2020 20:10:19 |
| Data point term sent to Coder | System | 07 Aug 2020 20:08:30 |
| User entered 'arthritis' | Brittany Belcher (b) (4) | 07 Aug 2020 20:07:46 |

US3302105

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:57:13

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

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 09:16:21 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:03:00 |
| User entered 'un UNK 1990' | (b) (4) Brittany Belcher (b) (4) | 07 Aug 2020 20:07:46 |

US3302105

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:57:13

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 09:16:21 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:03:00 |
| User entered '0' | (b) (4) Brittany Belcher (b) (4) | 07 Aug 2020 20:07:46 |

US3302105

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:57:13

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 09:16:21 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:03:00 |
| User entered 'Yes (Y)' | (b) (4) Brittany Belcher (b) (4) | 07 Aug 2020 20:07:46 |

US3302105

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:57:13

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

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 09:16:21 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:03:00 |
| User entered empty. | (b) (4) Brittany Belcher (b) (4) | 07 Aug 2020 20:07:46 |

US3302105

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:57:13

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 09:16:21 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:03:00 |
| User entered '0' | (b) (4) Brittany Belcher (b) (4) | 07 Aug 2020 20:07:46 |

US3302105

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:57:13

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 09:16:21 |
| User entered 'Jan 1990' | System | 07 Aug 2020 20:07:46 |

US3302105

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:57:13

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 09:16:21 |
| User entered '1990' | System | 07 Aug 2020 20:07:46 |

US3302105

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:57:13

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 09:16:21 |
| User entered empty. | System | 07 Aug 2020 20:07:46 |

US3302105

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:57:13

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 09:16:21 |
| User entered empty. | System | 07 Aug 2020 20:07:46 |

US3302105

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:57:13

Condition

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 09:16:21 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:03:00 |
| User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Upper respiratory tract infections, PT: Tonsillitis, LLT: Tonsillitis - version MedDRA\\23.0. | Coder Import (b) (4) | 07 Aug 2020 20:10:19 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 07 Aug 2020 20:10:19 |
| Data point term sent to Coder | System | 07 Aug 2020 20:08:33 |
| User entered 'tonsillitis' | Brittany Belcher (b) (4) | 07 Aug 2020 20:08:07 |

US3302105

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:57:13

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

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 09:16:21 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:03:00 |
| User entered 'un UNK 1953' | (b) (4) Brittany Belcher (b) (4) | 07 Aug 2020 20:08:07 |

US3302105

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:57:13

Start date completely unknown

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 09:16:21 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:03:00 |
| User entered '0' | (b) (4) Brittany Belcher (b) (4) | 07 Aug 2020 20:08:07 |

US3302105

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:57:13

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 09:16:21 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:03:00 |
| User entered 'No (N)' | (b) (4) Brittany Belcher (b) (4) | 07 Aug 2020 20:08:07 |

US3302105

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:57:13

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

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 09:16:21 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:03:00 |
| User entered 'un UNK 1953' | (b) (4) Brittany Belcher (b) (4) | 07 Aug 2020 20:08:07 |

US3302105

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:57:13

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 09:16:21 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:03:00 |
| User entered '0' | (b) (4) Brittany Belcher (b) (4) | 07 Aug 2020 20:08:07 |

US3302105

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:57:13

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 09:16:21 |
| User entered 'Jan 1953' | System | 07 Aug 2020 20:08:07 |

US3302105

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:57:13

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 09:16:21 |
| User entered '1953' | System | 07 Aug 2020 20:08:07 |

US3302105

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:57:13

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 09:16:21 |
| User entered 'Jan 1953' | System | 07 Aug 2020 20:08:07 |

US3302105

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:57:13

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 09:16:21 |
| User entered '1953' | System | 07 Aug 2020 20:08:07 |

US3302105

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:57:13

[Condition](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 09:16:21 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:03:00 |
| User closed query 'Per DM CLR: Please review this Condition and please note that this information is not reflected on the Childbearing Potential eCRF page. Please reconcile and update applicable details as appropriate. Otherwise, clarify.' (Site from DM). Query 'Per DM CLR: Please review this Condition and please note that this information is not reflected on the Childbearing Potential eCRF page. Please reconcile and update applicable details as appropriate. Otherwise, clarify.' answered with 'this is reflected ' (Site from DM). | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 06:23:13 |
| Query 'Per DM CLR: Please review this Condition and please note that this information is not reflected on the Childbearing Potential eCRF page. Please reconcile and update applicable details as appropriate. Otherwise, clarify.' answered with 'this is reflected ' (Site from DM). | Wendy Taylor (b) (4) | 27 Oct 2020 12:56:10 |
| User opened query 'Per DM CLR: Please review this Condition and please note that this information is not reflected on the Childbearing Potential eCRF page. Please reconcile and update applicable details as appropriate. Otherwise, clarify.' (Site from DM). | (b) (4), (b) (6) | 27 Oct 2020 11:32:13 |
| User coded data point as SOC: Social circumstances, HLGT: Age related factors, HLT: Age related issues, PT: Postmenopause, LLT: Postmenopause - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 15 Oct 2020 13:25:29 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 15 Oct 2020 13:25:29 |
| Data point term sent to Coder | System | 15 Oct 2020 13:24:33 |
| User entered 'Post Menopausal' | Wendy Taylor (b) (4) | 15 Oct 2020 13:24:18 |

US3302105

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:57:13

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

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 09:16:21 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:03:00 |
| User entered 'UN UNK 2000' | (b) (4) Wendy Taylor (b) (4) | 15 Oct 2020 13:24:18 |

US3302105

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:57:13

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 09:16:21 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:03:00 |
| User entered '0' | (b) (4) Wendy Taylor (b) (4) | 15 Oct 2020 13:24:18 |

US3302105

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:57:13

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 09:16:21 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:03:00 |
| User entered 'Yes (Y)' | (b) (4) Wendy Taylor (b) (4) | 15 Oct 2020 13:24:18 |

US3302105

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:57:13

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

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 09:16:21 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:03:00 |
| User entered empty. | Wendy Taylor (b) (4) | 15 Oct 2020 13:24:18 |

US3302105

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:57:13

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 09:16:21 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:03:00 |
| User entered '0' | (b) (4) Wendy Taylor (b) (4) | 15 Oct 2020 13:24:18 |

US3302105

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:57:13

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 09:16:21 |
| User entered 'Jan 2000' | System | 15 Oct 2020 13:24:18 |

US3302105

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:57:13

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 09:16:21 |
| User entered '2000' | System | 15 Oct 2020 13:24:18 |

US3302105

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:57:13

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 09:16:21 |
| User entered empty. | System | 15 Oct 2020 13:24:18 |

US3302105

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:57:13

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 09:16:21 |
| User entered empty. | System | 15 Oct 2020 13:24:18 |

US3302105

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:57:13

[Condition](#)

| Audit | User | Time (GMT) |
|---|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 09:16:21 |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| User coded data point as SOC: Surgical and medical procedures, HLGT: Head and neck therapeutic procedures, HLT: Tonsillar therapeutic procedures, PT: Tonsillectomy, LLT: Tonsillectomy - version MedDRA\\23.0. | Coder Import (b) (4) | 05 Apr 2021 14:28:28 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 05 Apr 2021 14:28:28 |
| Data point term sent to Coder | System | 05 Apr 2021 14:27:29 |
| User entered 'Tonsillectomy' | Brittany Belcher (b) (4) | 05 Apr 2021 14:27:06 |

US3302105

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:57:13

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

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 09:16:21 |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| User entered 'un UNK 1953' | (b) (4) Brittany Belcher (b) (4) | 05 Apr 2021 14:27:06 |

US3302105

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:57:13

Start date completely unknown

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 09:16:21 |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| User entered '0' | (b) (4) Brittany Belcher (b) (4) | 05 Apr 2021 14:27:06 |

US3302105

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:57:13

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 09:16:21 |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| User entered 'No (N)' | (b) (4) Brittany Belcher (b) (4) | 05 Apr 2021 14:27:06 |

US3302105

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:57:13

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

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 09:16:21 |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| User entered 'un UNK 1953' | (b) (4) Brittany Belcher (b) (4) | 05 Apr 2021 14:27:06 |

US3302105

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:57:13

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 09:16:21 |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| User entered '0' | (b) (4) Brittany Belcher (b) (4) | 05 Apr 2021 14:27:06 |

US3302105

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:57:13

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 09:16:21 |
| User entered 'Jan 1953' | System | 05 Apr 2021 14:27:06 |

US3302105

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:57:13

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 09:16:21 |
| User entered '1953' | System | 05 Apr 2021 14:27:06 |

US3302105

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:57:13

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 09:16:21 |
| User entered 'Jan 1953' | System | 05 Apr 2021 14:27:06 |

US3302105

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:57:13

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 09:16:21 |
| User entered '1953' | System | 05 Apr 2021 14:27:06 |

US3302105

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:57:13

[Condition](#)

| Audit | User | Time (GMT) |
|---|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 09:16:21 |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Knee arthroplasty, LLT: Partial knee replacement - version MedDRA\\23.0. | Coder Import (b) (4) | 05 Apr 2021 14:33:17 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0. | Coder Import (b) (4) | 05 Apr 2021 14:33:17 |
| Data point term sent to Coder | System | 05 Apr 2021 14:28:31 |
| User entered 'Knee Replacement (Right Knee)' | Brittany Belcher (b) (4) | 05 Apr 2021 14:27:35 |

US3302105

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:57:13

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

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 09:16:21 |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| User entered 'un UNK 2016' | (b) (4) Brittany Belcher (b) (4) | 05 Apr 2021 14:27:35 |

US3302105

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:57:13

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 09:16:21 |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| User entered '0' | (b) (4) Brittany Belcher (b) (4) | 05 Apr 2021 14:27:35 |

US3302105

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:57:13

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 09:16:21 |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| User entered 'No (N)' | (b) (4) Brittany Belcher (b) (4) | 05 Apr 2021 14:27:35 |

US3302105

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:57:13

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

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 09:16:21 |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| User entered 'un UNK 2016' | (b) (4) Brittany Belcher (b) (4) | 05 Apr 2021 14:27:35 |

US3302105

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:57:13

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 09:16:21 |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| User entered '0' | (b) (4) Brittany Belcher (b) (4) | 05 Apr 2021 14:27:35 |

US3302105

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:57:13

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 09:16:21 |
| User entered 'Jan 2016' | System | 05 Apr 2021 14:27:35 |

US3302105

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:57:13

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 09:16:21 |
| User entered '2016' | System | 05 Apr 2021 14:27:35 |

US3302105

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:57:13

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 09:16:21 |
| User entered 'Jan 2016' | System | 05 Apr 2021 14:27:35 |

US3302105

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:57:13

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 09:16:21 |
| User entered '2016' | System | 05 Apr 2021 14:27:35 |

US3302105

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:57:13

[Condition](#)

| Audit | User | Time (GMT) |
|---|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 09:16:21 |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Knee arthroplasty, LLT: Partial knee replacement - version MedDRA\\23.0. | Coder Import (b) (4) | 05 Apr 2021 14:33:17 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0. | Coder Import (b) (4) | 05 Apr 2021 14:33:17 |
| Data point term sent to Coder | System | 05 Apr 2021 14:28:30 |
| User entered 'Knee Replacement (Left Knee)' | Brittany Belcher (b) (4) | 05 Apr 2021 14:27:58 |

US3302105

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:57:13

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

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 09:16:21 |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| User entered 'un UNK 2016' | (b) (4) Brittany Belcher (b) (4) | 05 Apr 2021 14:27:58 |

US3302105

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:57:13

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 09:16:21 |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| User entered '0' | (b) (4) Brittany Belcher (b) (4) | 05 Apr 2021 14:27:58 |

US3302105

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:57:13

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 09:16:21 |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| User entered 'No (N)' | (b) (4) Brittany Belcher (b) (4) | 05 Apr 2021 14:27:58 |

US3302105

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:57:13

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

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 09:16:21 |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| User entered 'un UNK 2016' | (b) (4) Brittany Belcher (b) (4) | 05 Apr 2021 14:27:58 |

US3302105

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:57:13

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 09:16:21 |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| User entered '0' | (b) (4) Brittany Belcher (b) (4) | 05 Apr 2021 14:27:58 |

US3302105

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:57:13

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 09:16:21 |
| User entered 'Jan 2016' | System | 05 Apr 2021 14:27:58 |

US3302105

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:57:13

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 09:16:21 |
| User entered '2016' | System | 05 Apr 2021 14:27:58 |

US3302105

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:57:13

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 09:16:21 |
| User entered 'Jan 2016' | System | 05 Apr 2021 14:27:58 |

US3302105

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:57:13

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 09:16:21 |
| User entered '2016' | System | 05 Apr 2021 14:27:58 |

US3302105

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:57:13

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 09:16:21 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:03:00 |
| User entered 'Yes (Y)' | (b) (4) Brittany Belcher (b) (4) | 07 Aug 2020 21:08:19 |

US3302105

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:57:13

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 09:16:21 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:03:00 |
| User entered '07 Aug 2020' reason for change: Data Entry Error | (b) (4) | |
| | Brittany Belcher (b) (4) | 04 Nov 2020 18:22:20 |
| User entered '7 Aug 2020' | (b) (4) | |
| | Brittany Belcher (b) (4) | 07 Aug 2020 21:08:19 |

US3302105

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:57:13

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

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 09:16:21 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:03:00 |
| User entered '15:58' | (b) (4) Brittany Belcher (b) (4) | 07 Aug 2020 21:08:19 |

US3302105

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:57:13

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 09:16:21 |
| User entered '07 Aug 2020 15:58' | System | 04 Nov 2020 18:22:20 |
| User entered '7 Aug 2020 15:58' | System | 07 Aug 2020 21:08:19 |

US3302105

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:57:13

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

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 09:16:21 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:03:00 |
| User entered '67' in | (b) (4) Brittany Belcher (b) (4) | 07 Aug 2020 21:08:19 |
| DataPoint set to visible. | System | 07 Aug 2020 20:06:44 |

US3302105

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:57:13

Weight (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 09:16:21 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:03:00 |
| User entered '175' lb | (b) (4) Brittany Belcher (b) (4) | 07 Aug 2020 21:08:19 |
| DataPoint set to visible. | System | 07 Aug 2020 20:06:44 |

US3302105

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:57:13

BMI (xxx.x)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 09:16:21 |
| Amendment Manager: User entered '27.46618' | System | 16 Sep 2020 23:48:06 |
| User entered '27.5' | System | 07 Aug 2020 21:08:19 |
| DataPoint set to visible. | System | 07 Aug 2020 20:06:44 |

US3302105

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:57:13

[BMI units](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 09:16:21 |
| User entered 'kg/m2' | System | 07 Aug 2020 21:08:19 |
| DataPoint set to visible. | System | 07 Aug 2020 20:06:44 |

US3302105

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:57:13

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 09:16:21 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:03:00 |
| User closed query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly.' (Site from DM). | (b) (4) (b) (4), (b) (6) | 12 Oct 2020 06:17:16 |
| Query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly.' answered with 'updated' (Site from DM). | Brittany Belcher (b) (4) | 08 Oct 2020 12:39:18 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | Brittany Belcher (b) (4) | 05 Oct 2020 18:28:24 |
| User opened query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly.' (Site from DM). | (b) (4), (b) (6) | 28 Sep 2020 09:00:33 |
| User entered '97.5' F | Brittany Belcher (b) (4) | 07 Aug 2020 21:08:19 |

US3302105

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:57:13

[Route of measurement](#)

| Audit | User | Time (GMT) |
|--|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 09:16:21 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:03:00 |
| User entered empty; reason for change Data Entry Error | (b) (4) Brittany Belcher (b) (4) | 05 Oct 2020 18:28:24 |
| User entered 'Oral (Oral)' | Brittany Belcher (b) (4) | 07 Aug 2020 21:08:19 |

US3302105

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:57:13

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 09:16:21 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:03:00 |
| User entered empty. | (b) (4) Brittany Belcher (b) (4) | 07 Aug 2020 21:08:19 |

US3302105

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:57:13

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 09:16:21 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:03:00 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4) Brittany Belcher (b) (4) | 05 Oct 2020 18:28:24 |
| User entered '70' | Brittany Belcher (b) (4) | 07 Aug 2020 21:08:19 |

US3302105

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:57:13

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 09:16:21 |
| User entered 'bpm' | System | 07 Aug 2020 21:08:19 |

US3302105

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:57:13

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

| Audit | User | Time (GMT) |
|---|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 09:16:21 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:03:00 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4) Brittany Belcher (b) (4) | 05 Oct 2020 18:28:24 |
| User entered '16' | Brittany Belcher (b) (4) | 07 Aug 2020 21:08:19 |

US3302105

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:57:13

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 09:16:21 |
| User entered 'breaths/min' | System | 07 Aug 2020 21:08:19 |

US3302105

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:57:13

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 09:16:21 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:03:00 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4) Brittany Belcher (b) (4) | 05 Oct 2020 18:28:24 |
| User entered '135' | Brittany Belcher (b) (4) | 07 Aug 2020 21:08:19 |

US3302105

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:57:13

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 09:16:21 |
| User entered 'mmHg' | System | 07 Aug 2020 21:08:19 |

US3302105

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:57:13

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 09:16:21 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:03:00 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4) Brittany Belcher (b) (4) | 05 Oct 2020 18:28:24 |
| User entered '75' | Brittany Belcher (b) (4) | 07 Aug 2020 21:08:19 |

US3302105

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:57:13

[Diastolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 09:16:21 |
| User entered 'mmHg' | System | 07 Aug 2020 21:08:19 |

US3302105

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:57:13

[Height \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 09:16:21 |
| | | |

US3302105

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:57:13

Weight (derived)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 09:16:21 |

US3302105

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 16:57:13

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 09:16:21 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:03:00 |
| User entered 'Yes (Y)' | (b) (4) Brittany Belcher (b) (4) | 07 Aug 2020 21:08:28 |

US3302105

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 16:57:13

Date of examination (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 09:16:21 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:03:00 |
| User entered '07 Aug 2020' reason for change: Data Entry Error | (b) (4) Brittany Belcher (b) (4) | 04 Nov 2020 18:22:26 |
| Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System). | (b) (4), (b) (6) | 08 Sep 2020 05:20:56 |
| User opened query 'The Physical Examination Date isSystem prior to the Screening Visit Date. Please review and reconcile.' (Site from System). | | 04 Sep 2020 12:49:41 |
| User entered '7 Aug 2020' | Brittany Belcher (b) (4) | 07 Aug 2020 21:08:28 |

US3302105

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:57:13

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 09:16:21 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:03:00 |
| User entered '07 Aug 2020' reason for change: Data Entry Error | (b) (4) | |
| | Brittany Belcher (b) (4) | 04 Nov 2020 18:22:32 |
| User entered '7 Aug 2020' | (b) (4) | |
| | Brittany Belcher (b) (4) | 07 Aug 2020 21:08:56 |

US3302105

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:57:13

[Is the participant of childbearing potential?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 09:16:21 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:03:00 |
| User entered 'No (N)' | (b) (4) Brittany Belcher (b) (4) | 07 Aug 2020 21:08:56 |

US3302105

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:57:13

If No, what is the reason?

| Audit | User | Time (GMT) |
|---|-----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 09:16:21 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:03:00 |
| User closed query 'Per CDM re-query: Please add this condition under MH eCRF. Thank you!' (Site from DM). | (b) (4) (b) (4), (b) (6) | 16 Oct 2020 15:11:41 |
| Query 'Per CDM re-query: Please add this condition under MH eCRF. Thank you!' answered with 'updated ' (Site from DM). | Wendy Taylor (b) (4) | 15 Oct 2020 13:24:26 |
| User opened query 'Per CDM re-query: Please add this condition under MH eCRF. Thank you!' (Site from DM). | (b) (4), (b) (6) | 12 Oct 2020 07:21:30 |
| User closed query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate.' (Site from DM). | (b) (4), (b) (6) | 12 Oct 2020 07:21:14 |
| Query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate.' answered with 'ADDED' (Site from DM). | marsha gossett (b) (4) (b) (4) | 09 Oct 2020 13:34:15 |
| User opened query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate.' (Site from DM). | (b) (4), (b) (6) | 16 Sep 2020 11:40:09 |
| User entered 'Post-menopausal (POST-MENOPAUSAL)' | Brittany Belcher (b) (4) | 07 Aug 2020 21:08:56 |

US3302105

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:57:13

If Partner medically sterile or Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 09:16:21 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:03:00 |
| User entered empty. | (b) (4) | 07 Aug 2020 21:08:56 |

US3302105

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:57:13

If Surgically sterile, date of surgery (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 09:16:21 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:03:00 |
| User entered empty. | (b) (4) Brittany Belcher (b) (4) | 07 Aug 2020 21:08:56 |

US3302105

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:57:13

Date of surgery unknown

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 09:16:21 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:03:00 |
| User entered '0' | (b) (4) Brittany Belcher (b) (4) | 07 Aug 2020 21:08:56 |

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Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:57:13

If Post-menopausal, date of last menstruation (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 09:16:21 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:03:00 |
| User entered 'un UNK 2000' reason for change: Data Entry Error | (b) (4) Brittany Belcher (b) (4) | 29 Oct 2020 12:17:42 |
| User entered empty. | (b) (4) Brittany Belcher (b) (4) | 07 Aug 2020 21:08:56 |

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Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:57:13

Date of last menstruation unknown

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 09:16:21 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:03:00 |
| User closed query 'Per CDM re-query: Thank you for your answer. However, according to a MH, post-menopausal started on UnUnk2000, however here it is marked that date is unknown. Please review and update accordingly or clarify otherwise. Thank you' (Site from DM). | (b) (4), (b) (6) | 30 Oct 2020 11:12:00 |
| Query 'Per CDM re-query: Thank you for your answer. However, according to a MH, post-menopausal started on UnUnk2000, however here it is marked that date is unknown. Please review and update accordingly or clarify otherwise. Thank you' answered with 'done' (Site from DM). | Brittany Belcher (b) (4) | 29 Oct 2020 12:17:47 |
| User entered '0' reason for change: Data Entry Error | Brittany Belcher (b) (4) | 29 Oct 2020 12:17:42 |
| User opened query 'Per CDM re-query: Thank you for your answer. However, according to a MH, post-menopausal started on UnUnk2000, however here it is marked that date is unknown. Please review and update accordingly or clarify otherwise. Thank you' (Site from DM). | (b) (4), (b) (6) | 29 Oct 2020 06:08:18 |
| User closed query 'Per CDM: According to a MH, post-menopausal started on UnUnk2000, however here it is marked that date is unknown. Please review and update accordingly or clarify otherwise. Thank you!' (Site from DM). | (b) (4), (b) (6) | 29 Oct 2020 06:08:18 |
| Query 'Per CDM: According to a MH, post-menopausal started on UnUnk2000, however here it is marked that date is unknown. Please review and update accordingly or clarify otherwise. Thank you!' answered with 'last date is unknown ' (Site from DM). | Wendy Taylor (b) (4) | 28 Oct 2020 19:08:10 |
| User opened query 'Per CDM: According to a MH, post-menopausal started on UnUnk2000, however here it is marked that date is unknown. Please review and update accordingly or clarify otherwise. Thank you!' (Site from DM). | (b) (4), (b) (6) | 28 Oct 2020 06:23:06 |

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Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:57:13

Date of last menstruation unknown

| Audit | User | Time (GMT) |
|------------------|--------------------------|----------------------|
| User entered 'I' | Brittany Belcher (b) (4) | 07 Aug 2020 21:08:56 |
| | | |
| | | |

US3302105

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:57:13

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 09:16:21 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:03:00 |
| User entered 'Yes (Y)' | (b) (4) Brittany Belcher (b) (4) | 07 Aug 2020 20:07:04 |

US3302105

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:57:13

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 09:16:21 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:03:00 |
| User entered 'No (N)' | (b) (4) Brittany Belcher (b) (4) | 07 Aug 2020 20:07:04 |

US3302105

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:57:13

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 09:16:21 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:03:00 |
| User entered 'No (N)' | (b) (4) Brittany Belcher (b) (4) | 07 Aug 2020 20:07:04 |

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Folder: Screening

Form: Risk of Exposure

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Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 09:16:21 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:03:00 |
| User entered 'No (N)' | (b) (4) Brittany Belcher (b) (4) | 07 Aug 2020 20:07:04 |

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:57:13

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 09:16:21 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:03:00 |
| User entered 'No (N)' | (b) (4) Brittany Belcher (b) (4) | 07 Aug 2020 20:07:04 |

US3302105

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:57:13

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 09:16:21 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:03:00 |
| User entered 'No (N)' | (b) (4) Brittany Belcher (b) (4) | 07 Aug 2020 20:07:04 |

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Folder: Screening

Form: Risk of Exposure

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Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 09:16:21 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:03:00 |
| User entered 'No (N)' | Brittany Belcher (b) (4) | 07 Aug 2020 20:07:04 |

US3302105

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:57:13

[Personal Care and in-home services](#) (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 09:16:21 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:03:00 |
| User entered 'No (N)' | (b) (4) Brittany Belcher (b) (4) | 07 Aug 2020 20:07:04 |

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:57:13

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 09:16:21 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:03:00 |
| User entered 'No (N)' | (b) (4) Brittany Belcher (b) (4) | 07 Aug 2020 20:07:04 |

US3302105

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:57:13

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 09:16:21 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:03:00 |
| User entered 'No (N)' | Brittany Belcher (b) (4) | 07 Aug 2020 20:07:04 |

US3302105

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:57:13

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 09:16:21 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:03:00 |
| User entered 'No (N)' | Brittany Belcher (b) (4) | 07 Aug 2020 20:07:04 |

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Folder: Screening

Form: Risk of Exposure

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Other

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 09:16:21 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:03:00 |
| User entered 'No (N)' | (b) (4) Brittany Belcher (b) (4) | 07 Aug 2020 20:07:04 |

US3302105

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:57:13

[Specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 09:16:21 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:03:00 |
| User entered empty. | (b) (4) | 07 Aug 2020 20:07:04 |

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:57:13

No Risk Identified

| Audit | User | Time (GMT) |
|--|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 09:16:21 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:03:00 |
| User entered '0' reason for change: Data Entry Error | (b) (4) Brittany Belcher (b) (4) | 03 Nov 2020 16:19:30 |
| User entered '1' | (b) (4) Brittany Belcher (b) (4) | 07 Aug 2020 20:07:04 |

US3302105

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:57:13

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

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 09:16:21 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:03:00 |
| User entered '0' | (b) (4) Brittany Belcher (b) (4) | 07 Aug 2020 20:07:04 |

US3302105

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:57:13

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 09:16:21 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:03:00 |
| User entered '0' | Brittany Belcher (b) (4) | 07 Aug 2020 20:07:04 |

US3302105

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:57:13

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 09:16:21 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:03:00 |
| User entered '0' | (b) (4) Brittany Belcher (b) (4) | 07 Aug 2020 20:07:04 |

US3302105

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:57:13

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 09:16:21 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:03:00 |
| User entered '0' | Brittany Belcher (b) (4) | 07 Aug 2020 20:07:04 |

US3302105

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:57:13

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

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 09:16:21 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:03:00 |
| User entered '1' reason for change: Data Entry Error | (b) (4) | 03 Nov 2020 16:19:30 |
| User entered '0' | Brittany Belcher (b) (4) | 07 Aug 2020 20:07:04 |

US3302105

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:57:13

Other

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 09:16:21 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:03:00 |
| User entered '0' | (b) (4) Brittany Belcher (b) (4) | 07 Aug 2020 20:07:04 |

US3302105

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:57:13

[Specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 09:16:21 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:03:00 |
| User entered empty. | (b) (4) | 07 Aug 2020 20:07:04 |

US3302105

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:57:13

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:40 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:03:10 |
| User entered 'Yes (Y)' | (b) (4) Brittany Belcher (b) (4) | 07 Aug 2020 20:35:07 |

US3302105

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:57:13

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

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:40 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:03:10 |
| User entered '07 Aug 2020' reason for change: Data Entry Error | (b) (4) | |
| | Brittany Belcher (b) (4) | 04 Nov 2020 18:22:47 |
| User entered '7 Aug 2020' | (b) (4) | |
| | Brittany Belcher (b) (4) | 07 Aug 2020 20:35:07 |

US3302105

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:57:13

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

| Audit | User | Time (GMT) |
|--------------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:40 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:03:10 |
| User entered 'Clinic (Clinic)' | (b) (4) Brittany Belcher (b) (4) | 07 Aug 2020 20:35:07 |

US3302105

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:57:13

[Folder OID](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:40 |
| User entered 'VISIT1' | System | 07 Aug 2020 20:35:07 |

US3302105

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:57:13

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

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:40 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:03:10 |
| User entered '07 AUG 2020' | (b) (4) RWS_ENDPOINT ENDPOINT (b) (4) | 07 Aug 2020 20:24:07 |

US3302105

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:57:13

What was the participant's randomization number?

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:40 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:03:10 |
| Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System). | (b) (4) System | 21 Aug 2020 02:59:07 |
| Amendment Manager: Data point set to conformant. | System | 21 Aug 2020 02:59:07 |
| User opened query 'Data entered is non-conformant. Please correct.' (Site from System). | System | 07 Aug 2020 20:24:07 |
| User entered '185056' (non-conformant). | RWS_ENDPOINT ENDPOINT (b) (4) | 07 Aug 2020 20:24:07 |

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:57:13

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

| Audit | User | Time (GMT) |
|-------------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:40 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:03:10 |
| User entered '>=65 years (3)' | (b) (4) RWS_ENDPOINT ENDPOINT (b) (4) | 07 Aug 2020 20:24:07 |

US3302105

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:57:13

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) | 29 Mar 2021 02:20:40 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:03:10 |
| User entered 'No (N)' | (b) (4) Brittany Belcher (b) (4) | 07 Aug 2020 20:35:54 |

US3302105

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:57:13

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) | 29 Mar 2021 02:20:40 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:03:10 |
| User entered 'No (N)' | (b) (4) Brittany Belcher (b) (4) | 07 Aug 2020 20:35:54 |

US3302105

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:57:13

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

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:40 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:03:10 |
| User entered 'No (N)' | (b) (4) Brittany Belcher (b) (4) | 07 Aug 2020 20:35:54 |

US3302105

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:57:13

Diabetes (Type I, Type 2, or gestational)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:40 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:03:10 |
| User entered 'No (N)' | (b) (4) Brittany Belcher (b) (4) | 07 Aug 2020 20:35:54 |

US3302105

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:57:13

[Liver Disease](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:40 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:03:10 |
| User entered 'No (N)' | (b) (4) Brittany Belcher (b) (4) | 07 Aug 2020 20:35:54 |

US3302105

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:57:13

Height

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:40 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:03:10 |
| User closed query 'Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1.Please review and update accordingly.' (Site from DM). | (b) (4) (b) (4), (b) (6) | 12 Oct 2020 05:35:44 |
| Query 'Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1.Please review and update accordingly.' answered with 'updated' (Site from DM). | Wendy Taylor (b) (4) | 08 Oct 2020 13:33:49 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | Brittany Belcher (b) (4) | 05 Oct 2020 18:29:00 |
| User opened query 'Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1.Please review and update accordingly.' (Site from DM). | (b) (4), (b) (6) | 28 Sep 2020 09:00:16 |
| User entered '67' in | Brittany Belcher (b) (4) | 07 Aug 2020 21:13:24 |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:57:13

Weight

| Audit | User | Time (GMT) |
|---|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:40 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:03:10 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4) Brittany Belcher (b) (4) | 05 Oct 2020 18:29:00 |
| User entered '175' lb | Brittany Belcher (b) (4) | 07 Aug 2020 21:13:24 |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:57:13

Height

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:40 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:03:10 |
| User closed query 'Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1.Please review and update accordingly.' (Site from DM). | (b) (4) (b) (4), (b) (6) | 12 Oct 2020 05:35:44 |
| Query 'Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1.Please review and update accordingly.' answered with 'updated' (Site from DM). | Wendy Taylor (b) (4) | 08 Oct 2020 13:33:49 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | Brittany Belcher (b) (4) | 05 Oct 2020 18:29:00 |
| User opened query 'Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1.Please review and update accordingly.' (Site from DM). | (b) (4), (b) (6) | 28 Sep 2020 09:00:16 |
| User entered '67' in | Brittany Belcher (b) (4) | 07 Aug 2020 21:13:24 |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:57:13

Weight

| Audit | User | Time (GMT) |
|---|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:40 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:03:10 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4) Brittany Belcher (b) (4) | 05 Oct 2020 18:29:00 |
| User entered '175' lb | Brittany Belcher (b) (4) | 07 Aug 2020 21:13:24 |

US3302105

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:57:13

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:40 |
| User accepted default value 'Pre-Dose (PREDOSE)' | Brittany Belcher (b) (4) | 07 Aug 2020 21:13:24 |

US3302105

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:57:13

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|--|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:40 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:03:10 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | (b) (4) Brittany Belcher (b) (4) | 05 Oct 2020 18:29:00 |
| User entered 'No (N)' | Brittany Belcher (b) (4) | 07 Aug 2020 21:13:24 |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:57:13

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:40 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:03:10 |
| User entered '07 Aug 2020' reason for change: Data Entry Error | (b) (4) | |
| | Brittany Belcher (b) (4) | 04 Nov 2020 18:22:55 |
| User entered '7 Aug 2020' reason for change: Data Entry Error | Brittany Belcher (b) (4) | 05 Oct 2020 18:29:00 |
| User entered empty. | Brittany Belcher (b) (4) | 07 Aug 2020 21:13:24 |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:57:13

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

| Audit | User | Time (GMT) |
|--|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:40 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:03:10 |
| User entered '15:58' reason for change: Data Entry Error | (b) (4) Brittany Belcher (b) (4) | 05 Oct 2020 18:29:00 |
| User entered empty. | Brittany Belcher (b) (4) | 07 Aug 2020 21:13:24 |

US3302105

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:57:13

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:40 |
| User entered '07 Aug 2020 15:58' | System | 04 Nov 2020 18:22:55 |
| User entered '7 Aug 2020 15:58' | System | 05 Oct 2020 18:29:00 |
| User entered empty. | System | 07 Aug 2020 21:13:24 |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:57:13

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:40 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:03:10 |
| User entered '97.5' F reason for change: Data Entry Error | (b) (4) Brittany Belcher (b) (4) | 05 Oct 2020 18:29:00 |
| User entered empty. | Brittany Belcher (b) (4) | 07 Aug 2020 21:13:24 |

US3302105

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:57:13

[Route of measurement](#)

| Audit | User | Time (GMT) |
|--|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:40 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:03:10 |
| User entered 'Oral (Oral)' reason for change: Data Entry Error | (b) (4) Brittany Belcher (b) (4) | 05 Oct 2020 18:29:00 |
| User entered empty. | Brittany Belcher (b) (4) | 07 Aug 2020 21:13:24 |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:57:13

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:40 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:03:10 |
| User entered empty. | (b) (4) | 07 Aug 2020 21:13:24 |

US3302105

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:57:13

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:40 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:03:10 |
| User entered '70' reason for change: Data Entry Error | (b) (4) Brittany Belcher (b) (4) | 05 Oct 2020 18:29:00 |
| User entered empty. | (b) (4) Brittany Belcher (b) (4) | 07 Aug 2020 21:13:24 |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:57:13

[Pulse units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:40 |
| User entered 'bpm' | System | 05 Oct 2020 18:29:00 |
| User entered empty. | System | 07 Aug 2020 21:13:24 |

US3302105

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:57:13

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

| Audit | User | Time (GMT) |
|---|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:40 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:03:10 |
| User entered '16' reason for change: Data Entry Error | (b) (4) Brittany Belcher (b) (4) | 05 Oct 2020 18:29:00 |
| User entered empty. | (b) (4) Brittany Belcher (b) (4) | 07 Aug 2020 21:13:24 |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:57:13

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:40 |
| User entered 'breaths/min' | System | 05 Oct 2020 18:29:00 |
| User entered empty. | System | 07 Aug 2020 21:13:24 |

US3302105

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:57:13

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|--|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:40 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:03:10 |
| User entered '135' reason for change: Data Entry Error | (b) (4) Brittany Belcher (b) (4) | 05 Oct 2020 18:29:00 |
| User entered empty. | Brittany Belcher (b) (4) | 07 Aug 2020 21:13:24 |

US3302105

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:57:13

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:40 |
| User entered 'mmHg' | System | 05 Oct 2020 18:29:00 |
| User entered empty. | System | 07 Aug 2020 21:13:24 |

US3302105

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:57:13

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:40 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:03:10 |
| User entered '75' reason for change: Data Entry Error | (b) (4) Brittany Belcher (b) (4) | 05 Oct 2020 18:29:00 |
| User entered empty. | (b) (4) Brittany Belcher (b) (4) | 07 Aug 2020 21:13:24 |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:57:13

Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:40 |
| User entered 'mmHg' | System | 05 Oct 2020 18:29:00 |
| User entered empty. | System | 07 Aug 2020 21:13:24 |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:57:13

Height

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:40 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:03:10 |
| User closed query 'Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1.Please review and update accordingly.' (Site from DM). | (b) (4) (b) (4), (b) (6) | 12 Oct 2020 05:35:44 |
| Query 'Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1.Please review and update accordingly.' answered with 'updated' (Site from DM). | Wendy Taylor (b) (4) | 08 Oct 2020 13:33:49 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | Brittany Belcher (b) (4) | 05 Oct 2020 18:29:00 |
| User opened query 'Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1.Please review and update accordingly.' (Site from DM). | (b) (4), (b) (6) | 28 Sep 2020 09:00:16 |
| User entered '67' in | Brittany Belcher (b) (4) | 07 Aug 2020 21:13:24 |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:57:13

Weight

| Audit | User | Time (GMT) |
|---|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:40 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:03:10 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4) Brittany Belcher (b) (4) | 05 Oct 2020 18:29:00 |
| User entered '175' lb | Brittany Belcher (b) (4) | 07 Aug 2020 21:13:24 |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:57:13

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:40 |
| User accepted default value 'Post-Dose (POSTDOSE)' | Brittany Belcher (b) (4) | 07 Aug 2020 21:13:24 |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:57:13

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:40 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:03:10 |
| User entered 'Yes (Y)' | (b) (4) Brittany Belcher (b) (4) | 07 Aug 2020 21:13:24 |

US3302105

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:57:13

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:40 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:03:10 |
| User entered '07 Aug 2020' reason for change: Data Entry Error | (b) (4) | |
| | Brittany Belcher (b) (4) | 04 Nov 2020 18:22:55 |
| User entered '7 Aug 2020' | (b) (4) | |
| | Brittany Belcher (b) (4) | 07 Aug 2020 21:13:24 |

US3302105

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:57:13

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

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:40 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:03:10 |
| Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' canceled (Site from System). | (b) (4) (b) (4), (b) (6) | 17 Aug 2020 06:27:56 |
| User opened query 'Post-dose vital signs time is prior System to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System). | | 07 Aug 2020 21:13:24 |
| User entered '16:56' | Brittany Belcher (b) (4) | 07 Aug 2020 21:13:24 |

US3302105

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:57:13

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:40 |
| User entered '07 Aug 2020 16:56' | System | 04 Nov 2020 18:22:55 |
| User entered '7 Aug 2020 16:56' | System | 07 Aug 2020 21:13:24 |

US3302105

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:57:13

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:40 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:03:10 |
| User entered '97.5' F | (b) (4) | 07 Aug 2020 21:13:24 |

US3302105

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:57:13

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:40 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:03:10 |
| User entered 'Oral (Oral)' | (b) (4) | 07 Aug 2020 21:13:24 |

US3302105

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:57:13

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:40 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:03:10 |
| User entered empty. | (b) (4) | 07 Aug 2020 21:13:24 |

US3302105

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:57:13

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:40 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:03:10 |
| User entered '63' | (b) (4) Brittany Belcher (b) (4) | 07 Aug 2020 21:13:24 |

US3302105

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:57:13

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:40 |
| User entered 'bpm' | System | 07 Aug 2020 21:13:24 |

US3302105

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:57:13

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

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:40 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:03:10 |
| User entered '18' | (b) (4) Brittany Belcher (b) (4) | 07 Aug 2020 21:13:24 |

US3302105

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:57:13

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:40 |
| User entered 'breaths/min' | System | 07 Aug 2020 21:13:24 |

US3302105

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:57:13

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:40 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:03:10 |
| User entered '146' | (b) (4) Brittany Belcher (b) (4) | 07 Aug 2020 21:13:24 |

US3302105

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:57:13

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:40 |
| User entered 'mmHg' | System | 07 Aug 2020 21:13:24 |

US3302105

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:57:13

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:40 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:03:10 |
| User entered '83' | (b) (4) Brittany Belcher (b) (4) | 07 Aug 2020 21:13:24 |

US3302105

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:57:13

Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:40 |
| User entered 'mmHg' | System | 07 Aug 2020 21:13:24 |

US3302105

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 16:57:13

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:40 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:03:10 |
| User entered 'No (N)' | (b) (4) | 07 Aug 2020 21:09:31 |

US3302105

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 16:57:13

Date of examination (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:40 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:03:10 |
| User entered empty. | (b) (4) | 07 Aug 2020 21:09:31 |

US3302105

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:57:13

[Was study treatment given?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:40 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:03:00 |
| User entered 'Yes (Y)' | (b) (4) Brittany Belcher (b) (4) | 07 Aug 2020 20:36:16 |

US3302105

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:57:13

If No, reason not given

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:40 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:03:00 |
| User entered empty. | (b) (4) | 07 Aug 2020 20:36:16 |

US3302105

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:57:13

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

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:40 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:03:00 |
| User entered empty. | (b) (4) | 07 Aug 2020 20:36:16 |

US3302105

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:57:13

[What was the study treatment?](#)

| Audit | User | Time (GMT) |
|-------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:40 |
| User entered 'MRNA-1273 OR PLACEBO' | System | 07 Aug 2020 20:36:16 |

US3302105

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:57:13

What was the treatment date? (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:40 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:03:00 |
| User entered '07 Aug 2020' reason for change: Data Entry Error | (b) (4) | |
| | Brittany Belcher (b) (4) | 04 Nov 2020 18:23:06 |
| User entered '7 Aug 2020' | Brittany Belcher (b) (4) | 07 Aug 2020 20:36:16 |

US3302105

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:57:13

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

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:40 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:03:00 |
| User entered '16:26' | (b) (4) Brittany Belcher (b) (4) | 07 Aug 2020 20:36:16 |

US3302105

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:57:13

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:40 |
| User entered '07 Aug 2020 16:26' | System | 04 Nov 2020 18:23:06 |
| User entered '7 Aug 2020 16:26' | System | 07 Aug 2020 20:36:16 |

US3302105

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:57:13

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

| Audit | User | Time (GMT) |
|------------------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:40 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:03:00 |
| User entered 'Left Arm (LEFT ARM)' | (b) (4) Brittany Belcher (b) (4) | 07 Aug 2020 20:36:16 |

US3302105

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:57:13

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:40 |
| User entered 'ONCE' | System | 07 Aug 2020 20:36:16 |

US3302105

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:57:13

What was the route of administration for the study treatment?

| Audit | User | Time (GMT) |
|------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:40 |
| User entered 'INTRAMUSCULAR' | System | 07 Aug 2020 20:36:16 |

US3302105

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:57:13

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:40 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:03:10 |
| User entered 'Yes (Y)' | (b) (4) Brittany Belcher (b) (4) | 07 Aug 2020 21:13:40 |

US3302105

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:57:13

Collection date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:40 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:03:10 |
| User entered '07 Aug 2020' reason for change: Data Entry Error | (b) (4) | |
| | Brittany Belcher (b) (4) | 04 Nov 2020 18:23:12 |
| User entered '7 Aug 2020' | (b) (4) | |
| | Brittany Belcher (b) (4) | 07 Aug 2020 21:13:40 |

US3302105

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:57:13

Collection time (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:40 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:03:10 |
| User entered '16:11' | (b) (4) Brittany Belcher (b) (4) | 07 Aug 2020 21:13:40 |

US3302105

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:57:13

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:40 |
| User entered '07 Aug 2020 16:11' | System | 04 Nov 2020 18:23:12 |
| User entered '7 Aug 2020 16:11' | System | 07 Aug 2020 21:13:40 |

US3302105

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 16:57:13

Collection date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:40 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:03:00 |
| User entered '07 Aug 2020' reason for change: Data Entry Error | (b) (4) | |
| | Brittany Belcher (b) (4) | 04 Nov 2020 18:23:17 |
| User entered '7 Aug 2020' | (b) (4) | |
| | Brittany Belcher (b) (4) | 07 Aug 2020 21:13:57 |

US3302105

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:57:13

[Lab Test](#)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:40 |
| User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)' | Brittany Belcher (b) (4) | 07 Aug 2020 21:13:57 |

US3302105

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:57:13

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:40 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:03:00 |
| User entered 'Yes (Y)' | (b) (4) Brittany Belcher (b) (4) | 07 Aug 2020 21:13:57 |

US3302105

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:57:13

Collection time (00:00 - 23:59)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:40 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:03:00 |
| User entered '16:09' | (b) (4) | 07 Aug 2020 21:13:57 |

US3302105

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:57:13

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:40 |
| User entered '07 Aug 2020 16:09' | System | 04 Nov 2020 18:23:17 |
| User entered '7 Aug 2020 16:09' | System | 07 Aug 2020 21:13:57 |

US3302105

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:57:13

[Lab Test](#)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:40 |
| User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)' | Brittany Belcher (b) (4) | 07 Aug 2020 21:13:57 |

US3302105

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:57:13

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:40 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:03:00 |
| User entered 'No (N)' reason for change: Data Entry Error | (b) (4) Wendy Taylor (b) (4) | 23 Oct 2020 13:12:48 |
| User entered 'Yes (Y)' | Brittany Belcher (b) (4) | 07 Aug 2020 21:13:57 |

US3302105

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:57:13

Collection time (00:00 - 23:59)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:40 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:03:00 |
| User entered empty; reason for change Data Entry Error | (b) (4) Wendy Taylor (b) (4) | 23 Oct 2020 13:12:48 |
| User entered '16:09' | Brittany Belcher (b) (4) | 07 Aug 2020 21:13:57 |

US3302105

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:57:13

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

| Audit | User | Time (GMT) |
|---------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:40 |
| User entered empty. | System | 23 Oct 2020 13:12:48 |
| User entered '7 Aug 2020 16:09' | System | 07 Aug 2020 21:13:57 |

US3302105

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 16:57:13

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:40 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:03:00 |
| User entered 'Yes (Y)' | (b) (4) Brittany Belcher (b) (4) | 07 Aug 2020 21:14:01 |

US3302105

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 16:57:13

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:40 |
| User entered 'I' | System | 07 Aug 2020 21:14:01 |

US3302105

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| Data entry locked. | System | 07 Aug 2020 20:36:16 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 07 Aug 2020 20:36:16 |

US3302105

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:57:13

Was TEMPERATURE taken?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-08-07T16:47:53', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: 'b03e230b-10dc-4bba-8805-9b7b1bf1458e' User entered 'Yes (Y)' | System | 07 Aug 2020 20:48:20 |
| | System | 07 Aug 2020 20:48:20 |

US3302105

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:57:13

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-08-07T16:48:05', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: 'b03e230b-10dc-4bba-8805-9b7b1bf1458e' User entered '97.5' | System | 07 Aug 2020 20:48:20 |
| | System | 07 Aug 2020 20:48:20 |

US3302105

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:57:13

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-08-07T16:48:11', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: 'b03e230b-10dc-4bba-8805-9b7b1bf1458e' User entered 'No (N)' | System | 07 Aug 2020 20:48:20 |
| | System | 07 Aug 2020 20:48:20 |

US3302105

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:57:13

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-08-07T16:48:18', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: 'b03e230b-10dc-4bba-8805-9b7b1bf1458e' User entered '07 Aug 2020 16:48' | System | 07 Aug 2020 20:48:20 |
| | System | 07 Aug 2020 20:48:20 |

US3302105

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:57:13

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| User entered '07 Aug 2020 16:46' | System | 07 Aug 2020 20:36:16 |

US3302105

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:57:13

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| User entered '07 Aug 2020 19:16' | System | 07 Aug 2020 20:36:16 |

US3302105

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| Data entry locked. | System | 07 Aug 2020 20:36:16 |
| User entered 'Day 1, after vaccination (at home)' | System | 07 Aug 2020 20:36:16 |

US3302105

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:57:13

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| | | |

US3302105

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:57:13

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| | | |

US3302105

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:57:13

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

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| | | |

US3302105

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:57:13

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

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| | | |

US3302105

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:57:13

To **PREVENT** pain or fever from occurring

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| | | |

US3302105

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:57:13

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| | | |

US3302105

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:57:13

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| User entered '07 Aug 2020 20:11' | System | 07 Aug 2020 20:36:16 |

US3302105

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:57:13

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| User entered '08 Aug 2020 11:59' | System | 07 Aug 2020 20:36:16 |

US3302105

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| Data entry locked. | System | 07 Aug 2020 20:36:16 |
| User entered 'Day 2' | System | 07 Aug 2020 20:36:16 |

US3302105

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:57:13

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-08-08T20:52:34', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: 'eea2e1e8-95b1-4b21-a4f8-2dd496e6ee89' User entered 'Yes (Y)' | System | 09 Aug 2020 00:52:57 |
| | System | 09 Aug 2020 00:52:57 |

US3302105

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:57:13

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-08-08T20:52:43', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: 'eea2e1e8-95b1-4b21-a4f8-2dd496e6ee89' User entered '98.5' | System | 09 Aug 2020 00:52:57 |
| | System | 09 Aug 2020 00:52:57 |

US3302105

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:57:13

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-08-08T20:52:48', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: 'eea2e1e8-95b1-4b21-a4f8-2dd496e6ee89' User entered 'No (N)' | System | 09 Aug 2020 00:52:57 |
| | System | 09 Aug 2020 00:52:57 |

US3302105

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:57:13

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-08-08T20:52:55', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: 'eea2e1e8-95b1-4b21-a4f8-2dd496e6ee89' User entered '08 Aug 2020 20:52' | System | 09 Aug 2020 00:52:57 |
| | System | 09 Aug 2020 00:52:57 |

US3302105

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:57:13

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| User entered '08 Aug 2020 12:00' | System | 07 Aug 2020 20:36:16 |

US3302105

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:57:13

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| User entered '09 Aug 2020 11:59' | System | 07 Aug 2020 20:36:16 |

US3302105

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| Data entry locked. | System | 07 Aug 2020 20:36:16 |
| User entered 'Day 3' | System | 07 Aug 2020 20:36:16 |

US3302105

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:57:13

Was TEMPERATURE taken?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-08-09T22:10:37', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: 'a4a6d152-68ad-4c4f-b704-34c3de82248f' User entered 'Yes (Y)' | System | 10 Aug 2020 02:11:23 |
| | System | 10 Aug 2020 02:11:23 |

US3302105

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:57:13

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-08-09T22:11:09', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: 'a4a6d152-68ad-4c4f-b704-34c3de82248f' User entered '98.0' | System | 10 Aug 2020 02:11:23 |
| | System | 10 Aug 2020 02:11:23 |

US3302105

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:57:13

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-08-09T22:11:14', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: 'a4a6d152-68ad-4c4f-b704-34c3de82248f' User entered 'No (N)' | System | 10 Aug 2020 02:11:23 |
| | System | 10 Aug 2020 02:11:23 |

US3302105

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:57:13

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-08-09T22:11:21', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: 'a4a6d152-68ad-4c4f-b704-34c3de82248f' User entered '09 Aug 2020 22:11' | System | 10 Aug 2020 02:11:23 |
| | System | 10 Aug 2020 02:11:23 |

US3302105

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:57:13

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| User entered '09 Aug 2020 12:00' | System | 07 Aug 2020 20:36:16 |

US3302105

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:57:13

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| User entered '10 Aug 2020 11:59' | System | 07 Aug 2020 20:36:16 |

US3302105

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| Data entry locked. | System | 07 Aug 2020 20:36:16 |
| User entered 'Day 4' | System | 07 Aug 2020 20:36:16 |

US3302105

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:57:13

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-08-10T21:42:58', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '95b17dff-b9fb-4b37-a966-a7d5769be395' | System | 11 Aug 2020 01:43:22 |
| User entered 'Yes (Y)' | System | 11 Aug 2020 01:43:22 |

US3302105

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:57:13

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-08-10T21:43:07', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '95b17dff-b9fb-4b37-a966-a7d5769be395' User entered '97.0' | System | 11 Aug 2020 01:43:22 |
| | System | 11 Aug 2020 01:43:22 |

US3302105

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:57:13

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-08-10T21:43:12', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '95b17dff-b9fb-4b37-a966-a7d5769be395' | System | 11 Aug 2020 01:43:22 |
| User entered 'No (N)' | System | 11 Aug 2020 01:43:22 |

US3302105

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:57:13

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-08-10T21:43:18', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '95b17dff-b9fb-4b37-a966-a7d5769be395' | System | 11 Aug 2020 01:43:22 |
| User entered '10 Aug 2020 21:43' | System | 11 Aug 2020 01:43:22 |

US3302105

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:57:13

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| User entered '10 Aug 2020 12:00' | System | 07 Aug 2020 20:36:16 |

US3302105

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:57:13

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| User entered '11 Aug 2020 11:59' | System | 07 Aug 2020 20:36:16 |

US3302105

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| Data entry locked. | System | 07 Aug 2020 20:36:16 |
| User entered 'Day 5' | System | 07 Aug 2020 20:36:16 |

US3302105

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:57:13

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-08-11T22:31:30', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '1b95e985-3474-4d3f-a5ea-a008093f2ee3' | System | 12 Aug 2020 02:31:56 |
| User entered 'Yes (Y)' | System | 12 Aug 2020 02:31:56 |

US3302105

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:57:13

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-08-11T22:31:40', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '1b95e985-3474-4d3f-a5ea-a008093f2ee3' User entered '97.4' | System | 12 Aug 2020 02:31:56 |
| | System | 12 Aug 2020 02:31:56 |

US3302105

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:57:13

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-08-11T22:31:45', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '1b95e985-3474-4d3f-a5ea-a008093f2ee3' | System | 12 Aug 2020 02:31:56 |
| User entered 'No (N)' | System | 12 Aug 2020 02:31:56 |

US3302105

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:57:13

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-08-11T22:31:54', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '1b95e985-3474-4d3f-a5ea-a008093f2ee3' | System | 12 Aug 2020 02:31:56 |
| User entered '11 Aug 2020 22:31' | System | 12 Aug 2020 02:31:56 |

US3302105

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:57:13

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| User entered '11 Aug 2020 12:00' | System | 07 Aug 2020 20:36:16 |

US3302105

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:57:13

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| User entered '12 Aug 2020 11:59' | System | 07 Aug 2020 20:36:16 |

US3302105

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| Data entry locked. | System | 07 Aug 2020 20:36:16 |
| User entered 'Day 6' | System | 07 Aug 2020 20:36:16 |

US3302105

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:57:13

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| | | |

US3302105

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:57:13

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| | | |

US3302105

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:57:13

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

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| | | |

US3302105

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:57:13

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

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| | | |

US3302105

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:57:13

To **PREVENT** pain or fever from occurring

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| | | |

US3302105

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:57:13

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| | | |

US3302105

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:57:13

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| User entered '12 Aug 2020 12:00' | System | 07 Aug 2020 20:36:16 |

US3302105

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:57:13

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| User entered '13 Aug 2020 11:59' | System | 07 Aug 2020 20:36:16 |

US3302105

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| Data entry locked. | System | 07 Aug 2020 20:36:16 |
| User entered 'Day 7' | System | 07 Aug 2020 20:36:16 |

US3302105

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:57:13

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-08-13T23:01:39', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '68fd2a8b-26ac-4f11-99b4-a38c58b150e8' User entered 'Yes (Y)' | System | 14 Aug 2020 03:02:42 |
| | System | 14 Aug 2020 03:02:42 |

US3302105

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:57:13

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-08-13T23:02:29', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '68fd2a8b-26ac-4f11-99b4-a38c58b150e8' User entered '96.7' | System | 14 Aug 2020 03:02:42 |
| | System | 14 Aug 2020 03:02:42 |

US3302105

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:57:13

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-08-13T23:02:34', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '68fd2a8b-26ac-4f11-99b4-a38c58b150e8' | System | 14 Aug 2020 03:02:42 |
| User entered 'No (N)' | System | 14 Aug 2020 03:02:42 |

US3302105

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:57:13

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-08-13T23:02:40', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '68fd2a8b-26ac-4f11-99b4-a38c58b150e8' | System | 14 Aug 2020 03:02:42 |
| User entered '13 Aug 2020 23:02' | System | 14 Aug 2020 03:02:42 |

US3302105

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:57:13

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| User entered '13 Aug 2020 12:00' | System | 07 Aug 2020 20:36:16 |

US3302105

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:57:13

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| User entered '14 Aug 2020 11:59' | System | 07 Aug 2020 20:36:16 |

US3302105

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| Data entry locked. | System | 07 Aug 2020 20:36:16 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 07 Aug 2020 20:36:16 |

US3302105

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:57:13

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-08-07T16:48:29', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '749fc114-8236-406b-80fe-8ed7f557b38f' User entered 'None (1)' | System | 07 Aug 2020 20:48:58 |
| | System | 07 Aug 2020 20:48:58 |

US3302105

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:57:13

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-08-07T16:48:40', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '749fc114-8236-406b-80fe-8ed7f557b38f' User entered 'No (N)' | System | 07 Aug 2020 20:48:58 |
| | System | 07 Aug 2020 20:48:58 |

US3302105

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:57:13

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-08-07T16:48:44', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '749fc114-8236-406b-80fe-8ed7f557b38f' User entered 'No (N)' | System | 07 Aug 2020 20:48:58 |
| | System | 07 Aug 2020 20:48:58 |

US3302105

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:57:13

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-08-07T16:48:48', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '749fc114-8236-406b-80fe-8ed7f557b38f' User entered 'None (1)' | System | 07 Aug 2020 20:48:58 |
| | System | 07 Aug 2020 20:48:58 |

US3302105

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:57:13

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-08-07T16:48:56', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '749fc114-8236-406b-80fe-8ed7f557b38f' User entered '07 Aug 2020 16:48' | System | 07 Aug 2020 20:48:58 |
| | System | 07 Aug 2020 20:48:58 |

US3302105

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:57:13

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| User entered '07 Aug 2020 16:46' | System | 07 Aug 2020 20:36:16 |

US3302105

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:57:13

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| User entered '07 Aug 2020 19:16' | System | 07 Aug 2020 20:36:16 |

US3302105

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| Data entry locked. | System | 07 Aug 2020 20:36:16 |
| User entered 'Day 1, after vaccination (at home)' | System | 07 Aug 2020 20:36:16 |

US3302105

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:57:13

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

Please select one response below

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| | | |

US3302105

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:57:13

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| | | |

US3302105

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:57:13

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) | 25 Feb 2021 19:11:02 |
| | | |

US3302105

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:57:13

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

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| | | |

US3302105

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:57:13

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

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

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| | | |

US3302105

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:57:13

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

Please select one response below

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| | | |

US3302105

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:57:13

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| | | |

US3302105

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:57:13

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| User entered '07 Aug 2020 20:11' | System | 07 Aug 2020 20:36:16 |

US3302105

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:57:13

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| User entered '08 Aug 2020 11:59' | System | 07 Aug 2020 20:36:16 |

US3302105

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| Data entry locked. | System | 07 Aug 2020 20:36:16 |
| User entered 'Day 2' | System | 07 Aug 2020 20:36:16 |

US3302105

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:57:13

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-08-08T20:50:44', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '6a48cc82-0521-4979-9cd5-ebabda7322b0' | System | 09 Aug 2020 00:51:27 |
| User entered 'Does not interfere with activity (2)' | System | 09 Aug 2020 00:51:27 |

US3302105

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:57:13

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-08-08T20:50:48', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '6a48cc82-0521-4979-9cd5-ebabda7322b0' User entered 'No (N)' | System | 09 Aug 2020 00:51:27 |
| | System | 09 Aug 2020 00:51:27 |

US3302105

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:57:13

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-08-08T20:50:54', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '6a48cc82-0521-4979-9cd5-ebabda7322b0' | System | 09 Aug 2020 00:51:27 |
| User entered 'No (N)' | System | 09 Aug 2020 00:51:27 |

US3302105

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:57:13

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-08-08T20:50:59', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '6a48cc82-0521-4979-9cd5-ebabda7322b0' | System | 09 Aug 2020 00:51:27 |
| User entered 'None (1)' | System | 09 Aug 2020 00:51:27 |

US3302105

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:57:13

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-08-08T20:51:25', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '6a48cc82-0521-4979-9cd5-ebabda7322b0' User entered '08 Aug 2020 20:51' | System | 09 Aug 2020 00:51:27 |
| | System | 09 Aug 2020 00:51:27 |

US3302105

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:57:13

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| User entered '08 Aug 2020 12:00' | System | 07 Aug 2020 20:36:16 |

US3302105

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:57:13

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| User entered '09 Aug 2020 11:59' | System | 07 Aug 2020 20:36:16 |

US3302105

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| Data entry locked. | System | 07 Aug 2020 20:36:16 |
| User entered 'Day 3' | System | 07 Aug 2020 20:36:16 |

US3302105

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:57:13

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-08-09T22:07:29', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '17821288-8825-4236-a52c-85fcaac4ea81' | System | 10 Aug 2020 02:07:59 |
| User entered 'Does not interfere with activity (2)' | System | 10 Aug 2020 02:07:59 |

US3302105

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:57:13

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-08-09T22:07:32', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '17821288-8825-4236-a52c-85fcaac4ea81' | System | 10 Aug 2020 02:07:59 |
| User entered 'No (N)' | System | 10 Aug 2020 02:07:59 |

US3302105

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:57:13

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-08-09T22:07:36', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '17821288-8825-4236-a52c-85fcaac4ea81' User entered 'No (N)' | System | 10 Aug 2020 02:07:59 |
| | System | 10 Aug 2020 02:07:59 |

US3302105

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:57:13

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-08-09T22:07:45', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '17821288-8825-4236-a52c-85fcaac4ea81' User entered 'None (1)' | System | 10 Aug 2020 02:07:59 |
| | System | 10 Aug 2020 02:07:59 |

US3302105

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:57:13

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-08-09T22:07:54', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '17821288-8825-4236-a52c-85fcaac4ea81' User entered '09 Aug 2020 22:07' | System | 10 Aug 2020 02:07:59 |
| | System | 10 Aug 2020 02:07:59 |

US3302105

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:57:13

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| User entered '09 Aug 2020 12:00' | System | 07 Aug 2020 20:36:16 |

US3302105

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:57:13

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| User entered '10 Aug 2020 11:59' | System | 07 Aug 2020 20:36:16 |

US3302105

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| Data entry locked. | System | 07 Aug 2020 20:36:16 |
| User entered 'Day 4' | System | 07 Aug 2020 20:36:16 |

US3302105

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:57:13

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-08-10T21:43:25', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '74007a60-4a7d-4067-a7b3-1673c48b6700' | System | 11 Aug 2020 01:43:46 |
| User entered 'None (1)' | System | 11 Aug 2020 01:43:46 |

US3302105

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:57:13

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-08-10T21:43:29', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '74007a60-4a7d-4067-a7b3-1673c48b6700' | System | 11 Aug 2020 01:43:46 |
| User entered 'No (N)' | System | 11 Aug 2020 01:43:46 |

US3302105

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:57:13

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-08-10T21:43:33', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '74007a60-4a7d-4067-a7b3-1673c48b6700' | System | 11 Aug 2020 01:43:46 |
| User entered 'No (N)' | System | 11 Aug 2020 01:43:46 |

US3302105

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:57:13

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-08-10T21:43:36', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '74007a60-4a7d-4067-a7b3-1673c48b6700' | System | 11 Aug 2020 01:43:46 |
| User entered 'None (1)' | System | 11 Aug 2020 01:43:46 |

US3302105

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:57:13

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-08-10T21:43:45', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '74007a60-4a7d-4067-a7b3-1673c48b6700' | System | 11 Aug 2020 01:43:46 |
| User entered '10 Aug 2020 21:43' | System | 11 Aug 2020 01:43:46 |

US3302105

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:57:13

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| User entered '10 Aug 2020 12:00' | System | 07 Aug 2020 20:36:16 |

US3302105

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:57:13

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| User entered '11 Aug 2020 11:59' | System | 07 Aug 2020 20:36:16 |

US3302105

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| Data entry locked. | System | 07 Aug 2020 20:36:16 |
| User entered 'Day 5' | System | 07 Aug 2020 20:36:16 |

US3302105

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:57:13

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-08-11T22:30:10', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '4954f5f3-bfe8-4ec8-9157-7117c0fc6165' | System | 12 Aug 2020 02:30:41 |
| User entered 'None (1)' | System | 12 Aug 2020 02:30:41 |

US3302105

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:57:13

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-08-11T22:30:14', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '4954f5f3-bfe8-4ec8-9157-7117c0fc6165' | System | 12 Aug 2020 02:30:41 |
| User entered 'No (N)' | System | 12 Aug 2020 02:30:41 |

US3302105

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:57:13

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-08-11T22:30:23', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '4954f5f3-bfe8-4ec8-9157-7117c0fc6165' | System | 12 Aug 2020 02:30:41 |
| User entered 'No (N)' | System | 12 Aug 2020 02:30:41 |

US3302105

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:57:13

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-08-11T22:30:27', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '4954f5f3-bfe8-4ec8-9157-7117c0fc6165' | System | 12 Aug 2020 02:30:41 |
| User entered 'None (1)' | System | 12 Aug 2020 02:30:41 |

US3302105

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:57:13

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-08-11T22:30:36', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '4954f5f3-bfe8-4ec8-9157-7117c0fc6165' | System | 12 Aug 2020 02:30:41 |
| User entered '11 Aug 2020 22:30' | System | 12 Aug 2020 02:30:41 |

US3302105

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:57:13

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| User entered '11 Aug 2020 12:00' | System | 07 Aug 2020 20:36:16 |

US3302105

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:57:13

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| User entered '12 Aug 2020 11:59' | System | 07 Aug 2020 20:36:16 |

US3302105

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| Data entry locked. | System | 07 Aug 2020 20:36:16 |
| User entered 'Day 6' | System | 07 Aug 2020 20:36:16 |

US3302105

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:57:13

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

Please select one response below

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| | | |

US3302105

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:57:13

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| | | |

US3302105

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:57:13

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) | 25 Feb 2021 19:11:02 |
| | | |

US3302105

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:57:13

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

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| | | |

US3302105

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:57:13

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

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

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| | | |

US3302105

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:57:13

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

Please select one response below

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| | | |

US3302105

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:57:13

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| | | |

US3302105

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:57:13

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| User entered '12 Aug 2020 12:00' | System | 07 Aug 2020 20:36:16 |

US3302105

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:57:13

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| User entered '13 Aug 2020 11:59' | System | 07 Aug 2020 20:36:16 |

US3302105

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| Data entry locked. | System | 07 Aug 2020 20:36:16 |
| User entered 'Day 7' | System | 07 Aug 2020 20:36:16 |

US3302105

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:57:13

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-08-13T23:00:32', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '1e8b673f-74b5-48c3-8a3a-4d5ec040a9c4' | System | 14 Aug 2020 03:00:54 |
| User entered 'None (1)' | System | 14 Aug 2020 03:00:54 |

US3302105

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:57:13

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-08-13T23:00:36', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '1e8b673f-74b5-48c3-8a3a-4d5ec040a9c4' | System | 14 Aug 2020 03:00:54 |
| User entered 'No (N)' | System | 14 Aug 2020 03:00:54 |

US3302105

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:57:13

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-08-13T23:00:40', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '1e8b673f-74b5-48c3-8a3a-4d5ec040a9c4' | System | 14 Aug 2020 03:00:54 |
| User entered 'No (N)' | System | 14 Aug 2020 03:00:54 |

US3302105

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:57:13

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-08-13T23:00:45', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '1e8b673f-74b5-48c3-8a3a-4d5ec040a9c4' | System | 14 Aug 2020 03:00:54 |
| User entered 'None (1)' | System | 14 Aug 2020 03:00:54 |

US3302105

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:57:13

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-08-13T23:00:51', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '1e8b673f-74b5-48c3-8a3a-4d5ec040a9c4' | System | 14 Aug 2020 03:00:54 |
| User entered '13 Aug 2020 23:00' | System | 14 Aug 2020 03:00:54 |

US3302105

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:57:13

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| User entered '13 Aug 2020 12:00' | System | 07 Aug 2020 20:36:16 |

US3302105

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:57:13

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| User entered '14 Aug 2020 11:59' | System | 07 Aug 2020 20:36:16 |

US3302105

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| Data entry locked. | System | 07 Aug 2020 20:36:16 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 07 Aug 2020 20:36:16 |

US3302105

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:57:13

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-08-07T16:49:06', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: 'f0df8075-4a7a-4d46-91a1-4d30f8f1e431' User entered 'None (0)' | System | 07 Aug 2020 20:49:35 |
| | System | 07 Aug 2020 20:49:35 |

US3302105

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:57:13

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-08-07T16:49:09', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: 'f0df8075-4a7a-4d46-91a1-4d30f8f1e431' User entered 'None (0)' | System | 07 Aug 2020 20:49:35 |
| | System | 07 Aug 2020 20:49:35 |

US3302105

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:57:13

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-08-07T16:49:13', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: 'f0df8075-4a7a-4d46-91a1-4d30f8f1e431' User entered 'None (0)' | System | 07 Aug 2020 20:49:35 |
| | System | 07 Aug 2020 20:49:35 |

US3302105

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:57:13

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-08-07T16:49:16', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: 'f0df8075-4a7a-4d46-91a1-4d30f8f1e431' User entered 'None (0)' | System | 07 Aug 2020 20:49:35 |
| | System | 07 Aug 2020 20:49:35 |

US3302105

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:57:13

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-08-07T16:49:19', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: 'f0df8075-4a7a-4d46-91a1-4d30f8f1e431' User entered 'None (0)' | System | 07 Aug 2020 20:49:35 |
| | System | 07 Aug 2020 20:49:35 |

US3302105

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:57:13

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-08-07T16:49:21', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: 'f0df8075-4a7a-4d46-91a1-4d30f8f1e431' User entered 'None (0)' | System | 07 Aug 2020 20:49:35 |
| | System | 07 Aug 2020 20:49:35 |

US3302105

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:57:13

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) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-08-07T16:49:25', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: 'f0df8075-4a7a-4d46-91a1-4d30f8f1e431' | System | 07 Aug 2020 20:49:35 |
| User entered 'No (N)' | System | 07 Aug 2020 20:49:35 |

US3302105

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:57:13

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-08-07T16:49:32', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: 'f0df8075-4a7a-4d46-91a1-4d30f8f1e431' | System | 07 Aug 2020 20:49:35 |
| User entered '07 Aug 2020 16:49' | System | 07 Aug 2020 20:49:35 |

US3302105

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:57:13

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| User entered '07 Aug 2020 16:46' | System | 07 Aug 2020 20:36:16 |

US3302105

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:57:13

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| User entered '07 Aug 2020 19:16' | System | 07 Aug 2020 20:36:16 |

US3302105

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| Data entry locked. | System | 07 Aug 2020 20:36:16 |
| User entered 'Day 1, after vaccination (at home)' | System | 07 Aug 2020 20:36:16 |

US3302105

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:57:13

HEADACHE

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| | | |

US3302105

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:57:13

FATIGUE

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| | | |

US3302105

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:57:13

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| | | |

US3302105

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:57:13

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| | | |

US3302105

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:57:13

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| | | |

US3302105

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:57:13

CHILLS

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| | | |

US3302105

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:57:13

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) | 25 Feb 2021 19:11:02 |
| | | |

US3302105

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:57:13

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| | | |

US3302105

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:57:13

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| User entered '07 Aug 2020 20:11' | System | 07 Aug 2020 20:36:16 |

US3302105

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:57:13

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| User entered '08 Aug 2020 11:59' | System | 07 Aug 2020 20:36:16 |

US3302105

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| Data entry locked. | System | 07 Aug 2020 20:36:16 |
| User entered 'Day 2' | System | 07 Aug 2020 20:36:16 |

US3302105

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:57:13

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-08-08T20:51:36', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '142ee097-0f50-422c-8179-94f6fa011d45' | System | 09 Aug 2020 00:52:17 |
| User entered 'None (0)' | System | 09 Aug 2020 00:52:17 |

US3302105

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:57:13

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-08-08T20:51:46', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '142ee097-0f50-422c-8179-94f6fa011d45' | System | 09 Aug 2020 00:52:17 |
| User entered 'No interference with activity (1)' | System | 09 Aug 2020 00:52:17 |

US3302105

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:57:13

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-08-08T20:51:51', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '142ee097-0f50-422c-8179-94f6fa011d45' | System | 09 Aug 2020 00:52:17 |
| User entered 'None (0)' | System | 09 Aug 2020 00:52:17 |

US3302105

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:57:13

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-08-08T20:51:55', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '142ee097-0f50-422c-8179-94f6fa011d45' User entered 'None (0)' | System | 09 Aug 2020 00:52:17 |
| | System | 09 Aug 2020 00:52:17 |

US3302105

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:57:13

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-08-08T20:51:58', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '142ee097-0f50-422c-8179-94f6fa011d45' | System | 09 Aug 2020 00:52:17 |
| User entered 'None (0)' | System | 09 Aug 2020 00:52:17 |

US3302105

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:57:13

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-08-08T20:52:01', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '142ee097-0f50-422c-8179-94f6fa011d45' | System | 09 Aug 2020 00:52:17 |
| User entered 'None (0)' | System | 09 Aug 2020 00:52:17 |

US3302105

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:57:13

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) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-08-08T20:52:07', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '142ee097-0f50-422c-8179-94f6fa011d45' | System | 09 Aug 2020 00:52:17 |
| User entered 'No (N)' | System | 09 Aug 2020 00:52:17 |

US3302105

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:57:13

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-08-08T20:52:14', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '142ee097-0f50-422c-8179-94f6fa011d45' | System | 09 Aug 2020 00:52:17 |
| User entered '08 Aug 2020 20:52' | System | 09 Aug 2020 00:52:17 |

US3302105

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:57:13

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| User entered '08 Aug 2020 12:00' | System | 07 Aug 2020 20:36:16 |

US3302105

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:57:13

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| User entered '09 Aug 2020 11:59' | System | 07 Aug 2020 20:36:16 |

US3302105

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| Data entry locked. | System | 07 Aug 2020 20:36:16 |
| User entered 'Day 3' | System | 07 Aug 2020 20:36:16 |

US3302105

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:57:13

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-08-09T22:06:47', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '4cb73e99-8a27-4e26-9417-047e90e7d7e0' User entered 'None (0)' | System | 10 Aug 2020 02:07:26 |
| | System | 10 Aug 2020 02:07:26 |

US3302105

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:57:13

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-08-09T22:06:53', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '4cb73e99-8a27-4e26-9417-047e90e7d7e0' | System | 10 Aug 2020 02:07:26 |
| User entered 'No interference with activity (1)' | System | 10 Aug 2020 02:07:26 |

US3302105

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:57:13

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-08-09T22:06:57', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '4cb73e99-8a27-4e26-9417-047e90e7d7e0' User entered 'None (0)' | System | 10 Aug 2020 02:07:26 |
| | System | 10 Aug 2020 02:07:26 |

US3302105

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:57:13

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-08-09T22:07:01', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '4cb73e99-8a27-4e26-9417-047e90e7d7e0' User entered 'None (0)' | System | 10 Aug 2020 02:07:26 |
| | System | 10 Aug 2020 02:07:26 |

US3302105

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:57:13

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-08-09T22:07:04', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '4cb73e99-8a27-4e26-9417-047e90e7d7e0' User entered 'None (0)' | System | 10 Aug 2020 02:07:26 |
| | System | 10 Aug 2020 02:07:26 |

US3302105

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:57:13

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-08-09T22:07:07', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '4cb73e99-8a27-4e26-9417-047e90e7d7e0' User entered 'None (0)' | System | 10 Aug 2020 02:07:26 |
| | System | 10 Aug 2020 02:07:26 |

US3302105

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:57:13

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) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-08-09T22:07:12', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '4cb73e99-8a27-4e26-9417-047e90e7d7e0' User entered 'No (N)' | System | 10 Aug 2020 02:07:26 |
| | System | 10 Aug 2020 02:07:26 |

US3302105

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:57:13

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-08-09T22:07:22', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '4cb73e99-8a27-4e26-9417-047e90e7d7e0' User entered '09 Aug 2020 22:07' | System | 10 Aug 2020 02:07:26 |
| | System | 10 Aug 2020 02:07:26 |

US3302105

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:57:13

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| User entered '09 Aug 2020 12:00' | System | 07 Aug 2020 20:36:16 |

US3302105

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:57:13

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| User entered '10 Aug 2020 11:59' | System | 07 Aug 2020 20:36:16 |

US3302105

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| Data entry locked. | System | 07 Aug 2020 20:36:16 |
| User entered 'Day 4' | System | 07 Aug 2020 20:36:16 |

US3302105

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:57:13

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-08-10T21:43:53', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: 'f329207e-57b8-49b3-967c-9d605e861453' User entered 'None (0)' | System | 11 Aug 2020 01:44:26 |
| | System | 11 Aug 2020 01:44:26 |

US3302105

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:57:13

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-08-10T21:43:56', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: 'f329207e-57b8-49b3-967c-9d605e861453' User entered 'None (0)' | System | 11 Aug 2020 01:44:26 |
| | System | 11 Aug 2020 01:44:26 |

US3302105

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:57:13

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-08-10T21:43:58', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: 'f329207e-57b8-49b3-967c-9d605e861453' User entered 'None (0)' | System | 11 Aug 2020 01:44:26 |
| | System | 11 Aug 2020 01:44:26 |

US3302105

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:57:13

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-08-10T21:44:02', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: 'f329207e-57b8-49b3-967c-9d605e861453' User entered 'None (0)' | System | 11 Aug 2020 01:44:26 |
| | System | 11 Aug 2020 01:44:26 |

US3302105

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:57:13

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-08-10T21:44:05', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: 'f329207e-57b8-49b3-967c-9d605e861453' User entered 'None (0)' | System | 11 Aug 2020 01:44:26 |
| | System | 11 Aug 2020 01:44:26 |

US3302105

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:57:13

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-08-10T21:44:13', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: 'f329207e-57b8-49b3-967c-9d605e861453' User entered 'None (0)' | System | 11 Aug 2020 01:44:26 |
| | System | 11 Aug 2020 01:44:26 |

US3302105

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:57:13

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) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-08-10T21:44:16', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: 'f329207e-57b8-49b3-967c-9d605e861453' | System | 11 Aug 2020 01:44:26 |
| User entered 'No (N)' | System | 11 Aug 2020 01:44:26 |

US3302105

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:57:13

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-08-10T21:44:24', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: 'f329207e-57b8-49b3-967c-9d605e861453' User entered '10 Aug 2020 21:44' | System | 11 Aug 2020 01:44:26 |
| | System | 11 Aug 2020 01:44:26 |

US3302105

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:57:13

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| User entered '10 Aug 2020 12:00' | System | 07 Aug 2020 20:36:16 |

US3302105

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:57:13

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| User entered '11 Aug 2020 11:59' | System | 07 Aug 2020 20:36:16 |

US3302105

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| Data entry locked. | System | 07 Aug 2020 20:36:16 |
| User entered 'Day 5' | System | 07 Aug 2020 20:36:16 |

US3302105

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:57:13

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-08-11T22:30:45', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: 'a95e5f17-13e5-4137-afc1-774d8a82711e' User entered 'None (0)' | System | 12 Aug 2020 02:31:13 |
| | System | 12 Aug 2020 02:31:13 |

US3302105

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:57:13

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-08-11T22:30:49', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: 'a95e5f17-13e5-4137-afc1-774d8a82711e' User entered 'None (0)' | System | 12 Aug 2020 02:31:13 |
| | System | 12 Aug 2020 02:31:13 |

US3302105

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:57:13

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-08-11T22:30:52', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: 'a95e5f17-13e5-4137-afc1-774d8a82711e' User entered 'None (0)' | System | 12 Aug 2020 02:31:13 |
| | System | 12 Aug 2020 02:31:13 |

US3302105

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:57:13

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-08-11T22:30:56', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: 'a95e5f17-13e5-4137-afc1-774d8a82711e' User entered 'None (0)' | System | 12 Aug 2020 02:31:13 |
| | System | 12 Aug 2020 02:31:13 |

US3302105

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:57:13

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-08-11T22:30:59', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: 'a95e5f17-13e5-4137-afc1-774d8a82711e' User entered 'None (0)' | System | 12 Aug 2020 02:31:13 |
| | System | 12 Aug 2020 02:31:13 |

US3302105

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:57:13

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-08-11T22:31:02', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: 'a95e5f17-13e5-4137-afc1-774d8a82711e' User entered 'None (0)' | System | 12 Aug 2020 02:31:13 |
| | System | 12 Aug 2020 02:31:13 |

US3302105

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:57:13

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) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-08-11T22:31:07', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: 'a95e5f17-13e5-4137-afc1-774d8a82711e' User entered 'No (N)' | System | 12 Aug 2020 02:31:13 |
| | System | 12 Aug 2020 02:31:13 |

US3302105

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:57:13

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-08-11T22:31:11', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: 'a95e5f17-13e5-4137-afc1-774d8a82711e' User entered '11 Aug 2020 22:31' | System | 12 Aug 2020 02:31:13 |
| | System | 12 Aug 2020 02:31:13 |

US3302105

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:57:13

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| User entered '11 Aug 2020 12:00' | System | 07 Aug 2020 20:36:16 |

US3302105

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:57:13

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| User entered '12 Aug 2020 11:59' | System | 07 Aug 2020 20:36:16 |

US3302105

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| Data entry locked. | System | 07 Aug 2020 20:36:16 |
| User entered 'Day 6' | System | 07 Aug 2020 20:36:16 |

US3302105

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:57:13

HEADACHE

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| | | |

US3302105

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:57:13

FATIGUE

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| | | |

US3302105

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:57:13

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| | | |

US3302105

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:57:13

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| | | |

US3302105

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:57:13

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| | | |

US3302105

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:57:13

CHILLS

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| | | |

US3302105

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:57:13

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) | 25 Feb 2021 19:11:02 |
| | | |

US3302105

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:57:13

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| | | |

US3302105

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:57:13

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| User entered '12 Aug 2020 12:00' | System | 07 Aug 2020 20:36:16 |

US3302105

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:57:13

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| User entered '13 Aug 2020 11:59' | System | 07 Aug 2020 20:36:16 |

US3302105

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| Data entry locked. | System | 07 Aug 2020 20:36:16 |
| User entered 'Day 7' | System | 07 Aug 2020 20:36:16 |

US3302105

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:57:13

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-08-13T23:00:57', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: 'ad2ee11b-a21a-4f01-8223-1bb99cb003b6' User entered 'None (0)' | System | 14 Aug 2020 03:01:30 |
| | System | 14 Aug 2020 03:01:30 |

US3302105

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:57:13

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-08-13T23:01:00', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: 'ad2ee11b-a21a-4f01-8223-1bb99cb003b6' User entered 'None (0)' | System | 14 Aug 2020 03:01:30 |
| | System | 14 Aug 2020 03:01:30 |

US3302105

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:57:13

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-08-13T23:01:05', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: 'ad2ee11b-a21a-4f01-8223-1bb99cb003b6' User entered 'None (0)' | System | 14 Aug 2020 03:01:30 |
| | System | 14 Aug 2020 03:01:30 |

US3302105

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:57:13

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-08-13T23:01:10', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: 'ad2ee11b-a21a-4f01-8223-1bb99cb003b6' User entered 'None (0)' | System | 14 Aug 2020 03:01:30 |
| | System | 14 Aug 2020 03:01:30 |

US3302105

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:57:13

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-08-13T23:01:14', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: 'ad2ee11b-a21a-4f01-8223-1bb99cb003b6' User entered 'None (0)' | System | 14 Aug 2020 03:01:30 |
| | System | 14 Aug 2020 03:01:30 |

US3302105

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:57:13

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-08-13T23:01:17', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: 'ad2ee11b-a21a-4f01-8223-1bb99cb003b6' User entered 'None (0)' | System | 14 Aug 2020 03:01:30 |
| | System | 14 Aug 2020 03:01:30 |

US3302105

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:57:13

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) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-08-13T23:01:24', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: 'ad2ee11b-a21a-4f01-8223-1bb99cb003b6' User entered 'No (N)' | System | 14 Aug 2020 03:01:30 |
| | System | 14 Aug 2020 03:01:30 |

US3302105

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:57:13

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-08-13T23:01:29', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: 'ad2ee11b-a21a-4f01-8223-1bb99cb003b6' User entered '13 Aug 2020 23:01' | System | 14 Aug 2020 03:01:30 |
| | System | 14 Aug 2020 03:01:30 |

US3302105

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:57:13

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| User entered '13 Aug 2020 12:00' | System | 07 Aug 2020 20:36:16 |

US3302105

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:57:13

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| User entered '14 Aug 2020 11:59' | System | 07 Aug 2020 20:36:16 |

US3302105

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:57:13

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:40 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:03:00 |
| User entered 'Yes (Y)' | (b) (4) Wendy Taylor (b) (4) | 14 Aug 2020 15:19:16 |

US3302105

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:57:13

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:40 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:03:00 |
| User entered '14 Aug 2020' | (b) (4) Wendy Taylor (b) (4) | 14 Aug 2020 15:19:16 |

US3302105

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:57:13

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:40 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:03:00 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4) Wendy Taylor (b) (4) | 14 Aug 2020 15:19:16 |

US3302105

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:57:13

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:40 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:03:00 |
| User entered empty. | (b) (4) Wendy Taylor (b) (4) | 14 Aug 2020 15:19:16 |

US3302105

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:57:13

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:40 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:03:00 |
| User entered 'Yes (Y)' | (b) (4) Wendy Taylor (b) (4) | 14 Aug 2020 15:19:22 |

US3302105

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:57:13

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:40 |
| User entered 'I' | System | 14 Aug 2020 15:19:22 |

US3302105

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:57:13

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:40 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:02:55 |
| User entered 'Yes (Y)' | (b) (4) Wendy Taylor (b) (4) | 21 Aug 2020 20:44:31 |

US3302105

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:57:13

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:40 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:02:55 |
| User entered '21 Aug 2020' | (b) (4) Wendy Taylor (b) (4) | 21 Aug 2020 20:44:31 |

US3302105

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:57:13

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:40 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:02:55 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4) Wendy Taylor (b) (4) | 21 Aug 2020 20:44:31 |

US3302105

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:57:13

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:40 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:02:55 |
| User entered empty. | (b) (4) | 21 Aug 2020 20:44:31 |
| | Wendy Taylor (b) (4) | |
| | | |
| | | |

US3302105

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:57:13

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:40 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:02:55 |
| User entered 'Yes (Y)' | (b) (4) Wendy Taylor (b) (4) | 28 Aug 2020 22:20:05 |

US3302105

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:57:13

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:40 |
| User entered 'I' | System | 28 Aug 2020 22:20:05 |

US3302105

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:57:13

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:40 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:03:00 |
| User entered 'Yes (Y)' | (b) (4) Wendy Taylor (b) (4) | 28 Aug 2020 22:20:19 |

US3302105

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:57:13

Date of Contact or Contact Attempt (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:40 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:03:00 |
| User entered '28 Aug 2020' | Wendy Taylor (b) (4) | 28 Aug 2020 22:20:19 |

US3302105

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:57:13

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:40 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:03:00 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4) Wendy Taylor (b) (4) | 28 Aug 2020 22:20:19 |

US3302105

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:57:13

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:40 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:03:00 |
| User entered empty. | (b) (4) | 28 Aug 2020 22:20:19 |
| | Wendy Taylor (b) (4) | |
| | | |
| | | |

US3302105

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:57:13

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:40 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:03:00 |
| User entered 'Yes (Y)' | (b) (4) Wendy Taylor (b) (4) | 28 Aug 2020 22:20:29 |

US3302105

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:57:13

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:40 |
| User entered 'I' | System | 28 Aug 2020 22:20:29 |

US3302105

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:57:13

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:57 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:05:00 |
| User entered 'Yes (Y)' | (b) (4) Brittany Belcher (b) (4) | 04 Sep 2020 12:49:41 |

US3302105

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:57:13

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

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:57 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:05:00 |
| User entered '04 Sep 2020' reason for change: Data Entry Error | (b) (4) | |
| | Brittany Belcher (b) (4) | 04 Nov 2020 18:23:23 |
| User entered '4 Sep 2020' | (b) (4) | |
| | Brittany Belcher (b) (4) | 04 Sep 2020 12:49:41 |
| | (b) (4) | |
| | (b) (4) | |

US3302105

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:57:13

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

| Audit | User | Time (GMT) |
|--------------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:57 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:05:00 |
| User entered 'Clinic (Clinic)' | (b) (4) Brittany Belcher (b) (4) | 04 Sep 2020 12:49:41 |

US3302105

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:57:13

[Folder OID](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:57 |
| User entered 'VISIT2' | System | 04 Sep 2020 12:49:41 |

US3302105

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:57:13

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:57 |
| User accepted default value 'Pre-Dose (PREDOSE)' | Brittany Belcher (b) (4) | 04 Sep 2020 15:29:56 |

US3302105

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:57:13

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|--|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:57 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:05:00 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | (b) (4) Brittany Belcher (b) (4) | 17 Sep 2020 12:39:51 |
| User entered 'No (N)' | Brittany Belcher (b) (4) | 04 Sep 2020 15:29:56 |

US3302105

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:57:13

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:57 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:05:00 |
| User entered '04 Sep 2020' reason for change: Data Entry Error | (b) (4) | |
| | Brittany Belcher (b) (4) | 04 Nov 2020 18:23:33 |
| User entered '4 Sep 2020' reason for change: Data Entry Error | | |
| | Brittany Belcher (b) (4) | 17 Sep 2020 12:39:51 |
| User entered empty. | | |
| | Brittany Belcher (b) (4) | 04 Sep 2020 15:29:56 |

US3302105

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:57:13

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

| Audit | User | Time (GMT) |
|--|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:57 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:05:00 |
| User entered '08:07' reason for change: Data Entry Error | (b) (4) Brittany Belcher (b) (4) | 04 Nov 2020 18:23:33 |
| User entered '8:07' reason for change: Data Entry Error | Brittany Belcher (b) (4) | 17 Sep 2020 12:39:51 |
| User entered empty. | Brittany Belcher (b) (4) | 04 Sep 2020 15:29:56 |

US3302105

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:57:13

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:57 |
| User entered '04 Sep 2020 08:07' | System | 04 Nov 2020 18:23:33 |
| User entered '4 Sep 2020 8:07' | System | 17 Sep 2020 12:39:51 |
| User entered empty. | System | 04 Sep 2020 15:29:56 |

US3302105

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:57:13

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:57 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:05:00 |
| User entered '98.6' F reason for change: Data Entry Error | (b) (4) Brittany Belcher (b) (4) | 17 Sep 2020 12:39:51 |
| User entered empty. | Brittany Belcher (b) (4) | 04 Sep 2020 15:29:56 |

US3302105

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:57:13

[Route of measurement](#)

| Audit | User | Time (GMT) |
|--|------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:57 |
| User signature succeeded. | Gregory Feldman (b) (4) (b) (4) | 19 Feb 2021 18:05:00 |
| User entered 'Oral (Oral)' reason for change: Data Entry Error | Brittany Belcher (b) (4) | 17 Sep 2020 12:39:51 |
| User entered empty. | Brittany Belcher (b) (4) | 04 Sep 2020 15:29:56 |

US3302105

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:57:13

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:57 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:05:00 |
| User entered empty. | (b) (4) | 04 Sep 2020 15:29:56 |

US3302105

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:57:13

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:57 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:05:00 |
| User entered '77' reason for change: Data Entry Error | (b) (4) Brittany Belcher (b) (4) | 17 Sep 2020 12:39:51 |
| User entered empty. | Brittany Belcher (b) (4) | 04 Sep 2020 15:29:56 |

US3302105

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:57:13

[Pulse units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:57 |
| User entered 'bpm' | System | 17 Sep 2020 12:39:51 |
| User entered empty. | System | 04 Sep 2020 15:29:56 |

US3302105

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:57:13

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

| Audit | User | Time (GMT) |
|---|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:57 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:05:00 |
| User entered '16' reason for change: Data Entry Error | (b) (4) Brittany Belcher (b) (4) | 17 Sep 2020 12:39:51 |
| User entered empty. | (b) (4) Brittany Belcher (b) (4) | 04 Sep 2020 15:29:56 |

US3302105

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:57:13

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:57 |
| User entered 'breaths/min' | System | 17 Sep 2020 12:39:51 |
| User entered empty. | System | 04 Sep 2020 15:29:56 |

US3302105

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:57:13

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|--|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:57 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:05:00 |
| User entered '135' reason for change: Data Entry Error | (b) (4) Brittany Belcher (b) (4) | 17 Sep 2020 12:39:51 |
| User entered empty. | Brittany Belcher (b) (4) | 04 Sep 2020 15:29:56 |

US3302105

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:57:13

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:57 |
| User entered 'mmHg' | System | 17 Sep 2020 12:39:51 |
| User entered empty. | System | 04 Sep 2020 15:29:56 |

US3302105

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:57:13

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:57 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:05:00 |
| User entered '93' reason for change: Data Entry Error | (b) (4) Brittany Belcher (b) (4) | 17 Sep 2020 12:39:51 |
| User entered empty. | (b) (4) Brittany Belcher (b) (4) | 04 Sep 2020 15:29:56 |

US3302105

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:57:13

Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:57 |
| User entered 'mmHg' | System | 17 Sep 2020 12:39:51 |
| User entered empty. | System | 04 Sep 2020 15:29:56 |

US3302105

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:57:13

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:57 |
| User accepted default value 'Post-Dose (POSTDOSE)' | Brittany Belcher (b) (4) | 04 Sep 2020 15:29:56 |

US3302105

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:57:13

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:57 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:05:00 |
| User entered 'Yes (Y)' | (b) (4) Brittany Belcher (b) (4) | 04 Sep 2020 15:29:56 |

US3302105

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:57:13

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:57 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:05:00 |
| User entered '04 Sep 2020' reason for change: Data Entry Error | (b) (4) | |
| | Brittany Belcher (b) (4) | 04 Nov 2020 18:23:33 |
| User entered '4 Sep 2020' | (b) (4) | |
| | Brittany Belcher (b) (4) | 04 Sep 2020 15:29:56 |

US3302105

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:57:13

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

| Audit | User | Time (GMT) |
|--|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:57 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:05:00 |
| User entered '09:07' reason for change: Data Entry Error | (b) (4) Brittany Belcher (b) (4) | 04 Nov 2020 18:23:33 |
| User entered '9:07' | Brittany Belcher (b) (4) | 04 Sep 2020 15:29:56 |

US3302105

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:57:13

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:57 |
| User entered '04 Sep 2020 09:07' | System | 04 Nov 2020 18:23:33 |
| User entered '4 Sep 2020 9:07' | System | 04 Sep 2020 15:29:56 |

US3302105

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:57:13

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:57 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:05:00 |
| User entered '98.6' F | (b) (4) Brittany Belcher (b) (4) | 04 Sep 2020 15:29:56 |

US3302105

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:57:13

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:57 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:05:00 |
| User entered 'Oral (Oral)' | (b) (4) Brittany Belcher (b) (4) | 04 Sep 2020 15:29:56 |

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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:57:13

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:57 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:05:00 |
| User entered empty. | (b) (4) | 04 Sep 2020 15:29:56 |

US3302105

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:57:13

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:57 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:05:00 |
| User entered '65' | (b) (4) Brittany Belcher (b) (4) | 04 Sep 2020 15:29:56 |

US3302105

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:57:13

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:57 |
| User entered 'bpm' | System | 04 Sep 2020 15:29:56 |

US3302105

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:57:13

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

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:57 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:05:00 |
| User entered '18' | (b) (4) Brittany Belcher (b) (4) | 04 Sep 2020 15:29:56 |

US3302105

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:57:13

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:57 |
| User entered 'breaths/min' | System | 04 Sep 2020 15:29:56 |

US3302105

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:57:13

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:57 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:05:00 |
| User entered '146' | (b) (4) Brittany Belcher (b) (4) | 04 Sep 2020 15:29:56 |

US3302105

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:57:13

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:57 |
| User entered 'mmHg' | System | 04 Sep 2020 15:29:56 |

US3302105

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:57:13

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:57 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:05:00 |
| User entered '83' | (b) (4) Brittany Belcher (b) (4) | 04 Sep 2020 15:29:56 |

US3302105

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:57:13

Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:57 |
| User entered 'mmHg' | System | 04 Sep 2020 15:29:56 |

US3302105

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:57:13

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:57 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:05:00 |
| User entered 'Yes (Y)' | (b) (4) Brittany Belcher (b) (4) | 04 Sep 2020 12:50:14 |

US3302105

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:57:13

Date of examination (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:57 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:05:00 |
| User entered '04 Sep 2020' reason for change: Data Entry Error | (b) (4) | |
| | Brittany Belcher (b) (4) | 04 Nov 2020 18:23:37 |
| User entered '4 Sep 2020' | (b) (4) | |
| | Brittany Belcher (b) (4) | 04 Sep 2020 12:50:14 |

US3302105

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:57:13

[Was study treatment given?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:40 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:05:00 |
| User entered 'Yes (Y)' | (b) (4) Brittany Belcher (b) (4) | 04 Sep 2020 12:50:27 |

US3302105

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:57:13

[If No, reason not given](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:40 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:05:00 |
| User entered empty. | (b) (4) | 04 Sep 2020 12:50:27 |

US3302105

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:57:13

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

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:40 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:05:00 |
| User entered empty. | Brittany Belcher (b) (4) | 04 Sep 2020 12:50:27 |

US3302105

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:57:13

[What was the study treatment?](#)

| Audit | User | Time (GMT) |
|-------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:40 |
| User entered 'MRNA-1273 OR PLACEBO' | System | 04 Sep 2020 12:50:27 |

US3302105

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:57:13

What was the treatment date? (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:40 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:05:00 |
| User entered '04 Sep 2020' reason for change: Data Entry Error | (b) (4) | |
| | Brittany Belcher (b) (4) | 04 Nov 2020 18:23:45 |
| User entered '4 Sep 2020' | (b) (4) | |
| | Brittany Belcher (b) (4) | 04 Sep 2020 12:50:27 |

US3302105

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:57:13

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

| Audit | User | Time (GMT) |
|--|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:40 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:05:00 |
| User entered '08:37' reason for change: Data Entry Error | (b) (4) Brittany Belcher (b) (4) | 04 Nov 2020 18:23:45 |
| User entered '8:37' | Brittany Belcher (b) (4) | 04 Sep 2020 12:50:27 |

US3302105

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:57:13

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:40 |
| User entered '04 Sep 2020 08:37' | System | 04 Nov 2020 18:23:45 |
| User entered '4 Sep 2020 8:37' | System | 04 Sep 2020 12:50:27 |

US3302105

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:57:13

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

| Audit | User | Time (GMT) |
|------------------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:40 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:05:00 |
| User entered 'Left Arm (LEFT ARM)' | (b) (4) Brittany Belcher (b) (4) | 04 Sep 2020 12:50:27 |

US3302105

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:57:13

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:40 |
| User entered 'ONCE' | System | 04 Sep 2020 12:50:27 |

US3302105

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:57:13

What was the route of administration for the study treatment?

| Audit | User | Time (GMT) |
|------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:40 |
| User entered 'INTRAMUSCULAR' | System | 04 Sep 2020 12:50:27 |

US3302105

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:57:13

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:40 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:05:00 |
| User entered 'Yes (Y)' | (b) (4) Brittany Belcher (b) (4) | 04 Sep 2020 15:30:07 |

US3302105

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:57:13

Collection date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:40 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:05:00 |
| User entered '04 Sep 2020' reason for change: Data Entry Error | (b) (4) Brittany Belcher (b) (4) | 04 Nov 2020 18:23:50 |
| User entered '4 Sep 2020' | (b) (4) Brittany Belcher (b) (4) | 04 Sep 2020 15:30:07 |

US3302105

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:57:13

Collection time (00:00-23:59)

| Audit | User | Time (GMT) |
|--|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:40 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:05:00 |
| User entered '08:20' reason for change: Data Entry Error | (b) (4) Brittany Belcher (b) (4) | 04 Nov 2020 18:23:50 |
| User entered '8:20' | Brittany Belcher (b) (4) | 04 Sep 2020 15:30:07 |

US3302105

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:57:13

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:40 |
| User entered '04 Sep 2020 08:20' | System | 04 Nov 2020 18:23:50 |
| User entered '4 Sep 2020 8:20' | System | 04 Sep 2020 15:30:07 |

US3302105

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 16:57:13

Collection date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:40 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:03:10 |
| User entered '04 Sep 2020' reason for change: Data Entry Error | (b) (4) | |
| | Brittany Belcher (b) (4) | 04 Nov 2020 18:23:58 |
| User entered '4 Sep 2020' | (b) (4) | 04 Sep 2020 15:30:19 |

US3302105

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:57:13

[Lab Test](#)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:40 |
| User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)' | Brittany Belcher (b) (4) | 04 Sep 2020 15:30:19 |

US3302105

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:57:13

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:40 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:03:10 |
| User entered 'Yes (Y)' | (b) (4) Brittany Belcher (b) (4) | 04 Sep 2020 15:30:19 |

US3302105

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:57:13

Collection time (00:00 - 23:59)

| Audit | User | Time (GMT) |
|--|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:40 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:03:10 |
| User entered '08:17' reason for change: Data Entry Error | (b) (4) Brittany Belcher (b) (4) | 04 Nov 2020 18:23:58 |
| User entered '8:17' | Brittany Belcher (b) (4) | 04 Sep 2020 15:30:19 |

US3302105

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:57:13

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:40 |
| User entered '04 Sep 2020 08:17' | System | 04 Nov 2020 18:23:58 |
| User entered '4 Sep 2020 8:17' | System | 04 Sep 2020 15:30:19 |

US3302105

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:57:13

[Lab Test](#)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:40 |
| User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)' | Brittany Belcher (b) (4) | 04 Sep 2020 15:30:19 |

US3302105

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:57:13

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:40 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:03:10 |
| User entered 'Yes (Y)' | (b) (4) Brittany Belcher (b) (4) | 04 Sep 2020 15:30:19 |

US3302105

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:57:13

Collection time (00:00 - 23:59)

| Audit | User | Time (GMT) |
|--|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:40 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:03:10 |
| User entered '08:17' reason for change: Data Entry Error | (b) (4) Brittany Belcher (b) (4) | 04 Nov 2020 18:23:58 |
| User entered '8:17' | Brittany Belcher (b) (4) | 04 Sep 2020 15:30:19 |

US3302105

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:57:13

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:40 |
| User entered '04 Sep 2020 08:17' | System | 04 Nov 2020 18:23:58 |
| User entered '4 Sep 2020 8:17' | System | 04 Sep 2020 15:30:19 |

US3302105

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:57:13

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:40 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:05:00 |
| User entered 'Yes (Y)' | (b) (4) Brittany Belcher (b) (4) | 04 Sep 2020 15:30:23 |

US3302105

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:57:13

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:40 |
| User entered 'I' | System | 04 Sep 2020 15:30:23 |

US3302105

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| Data entry locked. | System | 04 Sep 2020 12:50:27 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 04 Sep 2020 12:50:27 |

US3302105

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:57:13

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-09-04T08:59:29', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: 'dc4ea303-e093-4f39-9c8a-d6db81590626' User entered 'Yes (Y)' | System | 04 Sep 2020 12:59:55 |
| | System | 04 Sep 2020 12:59:55 |

US3302105

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:57:13

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-09-04T08:59:44', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: 'dc4ea303-e093-4f39-9c8a-d6db81590626' User entered '98.6' | System | 04 Sep 2020 12:59:55 |
| | System | 04 Sep 2020 12:59:55 |

US3302105

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:57:13

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-09-04T08:59:49', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: 'dc4ea303-e093-4f39-9c8a-d6db81590626' User entered 'No (N)' | System | 04 Sep 2020 12:59:55 |
| | System | 04 Sep 2020 12:59:55 |

US3302105

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:57:13

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-09-04T08:59:53', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: 'dc4ea303-e093-4f39-9c8a-d6db81590626' User entered '04 Sep 2020 08:59' | System | 04 Sep 2020 12:59:55 |
| | System | 04 Sep 2020 12:59:55 |

US3302105

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:57:13

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| User entered '04 Sep 2020 08:57' | System | 04 Sep 2020 12:50:27 |

US3302105

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:57:13

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| User entered '04 Sep 2020 11:27' | System | 04 Sep 2020 12:50:27 |

US3302105

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| Data entry locked. | System | 04 Sep 2020 12:50:27 |
| User entered 'Day 1, after vaccination (at home)' | System | 04 Sep 2020 12:50:27 |

US3302105

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:57:13

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| | | |

US3302105

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:57:13

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| | | |

US3302105

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:57:13

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

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| | | |

US3302105

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:57:13

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

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| | | |

US3302105

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:57:13

To **PREVENT** pain or fever from occurring

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| | | |

US3302105

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:57:13

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| | | |

US3302105

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:57:13

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| User entered '04 Sep 2020 12:22' | System | 04 Sep 2020 12:50:27 |

US3302105

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:57:13

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| User entered '05 Sep 2020 11:59' | System | 04 Sep 2020 12:50:27 |

US3302105

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| Data entry locked. | System | 04 Sep 2020 12:50:27 |
| User entered 'Day 2' | System | 04 Sep 2020 12:50:27 |

US3302105

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:57:13

Was TEMPERATURE taken?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-09-05T19:04:51', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '338e3545-0abf-44da-8344-da0fe878593a' User entered 'Yes (Y)' | System | 05 Sep 2020 23:05:13 |
| | System | 05 Sep 2020 23:05:13 |

US3302105

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:57:13

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-09-05T19:04:59', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '338e3545-0abf-44da-8344-da0fe878593a' User entered '98.2' | System | 05 Sep 2020 23:05:13 |
| | System | 05 Sep 2020 23:05:13 |

US3302105

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:57:13

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-09-05T19:05:03', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '338e3545-0abf-44da-8344-da0fe878593a' User entered 'No (N)' | System | 05 Sep 2020 23:05:13 |
| | System | 05 Sep 2020 23:05:13 |

US3302105

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:57:13

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-09-05T19:05:09', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '338e3545-0abf-44da-8344-da0fe878593a' User entered '05 Sep 2020 19:05' | System | 05 Sep 2020 23:05:13 |
| | System | 05 Sep 2020 23:05:13 |

US3302105

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:57:13

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| User entered '05 Sep 2020 12:00' | System | 04 Sep 2020 12:50:27 |

US3302105

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:57:13

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| User entered '06 Sep 2020 11:59' | System | 04 Sep 2020 12:50:27 |

US3302105

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| Data entry locked. | System | 04 Sep 2020 12:50:27 |
| User entered 'Day 3' | System | 04 Sep 2020 12:50:27 |

US3302105

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:57:13

Was TEMPERATURE taken?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-09-06T22:07:13', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: 'c28ea8b5-017a-4f41-98a7-3a2a9b991bd5' User entered 'Yes (Y)' | System | 07 Sep 2020 02:07:37 |
| | System | 07 Sep 2020 02:07:37 |

US3302105

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:57:13

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-09-06T22:07:21', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: 'c28ea8b5-017a-4f41-98a7-3a2a9b991bd5' User entered '98.2' | System | 07 Sep 2020 02:07:37 |
| | System | 07 Sep 2020 02:07:37 |

US3302105

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:57:13

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-09-06T22:07:24', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: 'c28ea8b5-017a-4f41-98a7-3a2a9b991bd5' User entered 'No (N)' | System | 07 Sep 2020 02:07:37 |
| | System | 07 Sep 2020 02:07:37 |

US3302105

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:57:13

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-09-06T22:07:31', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: 'c28ea8b5-017a-4f41-98a7-3a2a9b991bd5' User entered '06 Sep 2020 22:07' | System | 07 Sep 2020 02:07:37 |
| | System | 07 Sep 2020 02:07:37 |

US3302105

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:57:13

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| User entered '06 Sep 2020 12:00' | System | 04 Sep 2020 12:50:27 |

US3302105

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:57:13

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| User entered '07 Sep 2020 11:59' | System | 04 Sep 2020 12:50:27 |

US3302105

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| Data entry locked. | System | 04 Sep 2020 12:50:27 |
| User entered 'Day 4' | System | 04 Sep 2020 12:50:27 |

US3302105

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:57:13

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-09-08T06:50:18', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '580a67e6-760a-423d-a1f7-cc6f81deafbb' User entered 'Yes (Y)' | System | 08 Sep 2020 10:50:39 |
| | System | 08 Sep 2020 10:50:39 |

US3302105

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:57:13

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-09-08T06:50:28', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '580a67e6-760a-423d-a1f7-cc6f81deafbb' User entered '97.2' | System | 08 Sep 2020 10:50:39 |
| | System | 08 Sep 2020 10:50:39 |

US3302105

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:57:13

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-09-08T06:50:31', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '580a67e6-760a-423d-a1f7-cc6f81deafbb' User entered 'No (N)' | System | 08 Sep 2020 10:50:39 |
| | System | 08 Sep 2020 10:50:39 |

US3302105

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:57:13

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-09-08T06:50:35', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '580a67e6-760a-423d-a1f7-cc6f81deafbb' User entered '08 Sep 2020 06:50' | System | 08 Sep 2020 10:50:39 |
| | System | 08 Sep 2020 10:50:39 |

US3302105

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:57:13

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| User entered '07 Sep 2020 12:00' | System | 04 Sep 2020 12:50:27 |

US3302105

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:57:13

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| User entered '08 Sep 2020 11:59' | System | 04 Sep 2020 12:50:27 |

US3302105

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| Data entry locked. | System | 04 Sep 2020 12:50:27 |
| User entered 'Day 5' | System | 04 Sep 2020 12:50:27 |

US3302105

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:57:13

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| | | |

US3302105

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:57:13

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| | | |

US3302105

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:57:13

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

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| | | |

US3302105

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:57:13

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

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| | | |

US3302105

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:57:13

To **PREVENT** pain or fever from occurring

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| | | |

US3302105

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:57:13

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| | | |

US3302105

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:57:13

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| User entered '08 Sep 2020 12:00' | System | 04 Sep 2020 12:50:27 |

US3302105

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:57:13

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| User entered '09 Sep 2020 11:59' | System | 04 Sep 2020 12:50:27 |

US3302105

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| Data entry locked. | System | 04 Sep 2020 12:50:27 |
| User entered 'Day 6' | System | 04 Sep 2020 12:50:27 |

US3302105

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:57:13

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-09-10T06:29:57', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '5d66c111-ecae-4166-aa11-e3f3b77d4646' User entered 'Yes (Y)' | System | 10 Sep 2020 10:30:23 |
| | System | 10 Sep 2020 10:30:23 |

US3302105

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:57:13

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-09-10T06:30:08', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '5d66c111-ecae-4166-aa11-e3f3b77d4646' User entered '97.8' | System | 10 Sep 2020 10:30:23 |
| | System | 10 Sep 2020 10:30:23 |

US3302105

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:57:13

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-09-10T06:30:15', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '5d66c111-ecae-4166-aa11-e3f3b77d4646' | System | 10 Sep 2020 10:30:23 |
| User entered 'No (N)' | System | 10 Sep 2020 10:30:23 |

US3302105

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:57:13

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-09-10T06:30:21', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '5d66c111-ecae-4166-aa11-e3f3b77d4646' | System | 10 Sep 2020 10:30:23 |
| User entered '10 Sep 2020 06:30' | System | 10 Sep 2020 10:30:23 |

US3302105

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:57:13

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| User entered '09 Sep 2020 12:00' | System | 04 Sep 2020 12:50:27 |

US3302105

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:57:13

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| User entered '10 Sep 2020 11:59' | System | 04 Sep 2020 12:50:27 |

US3302105

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| Data entry locked. | System | 04 Sep 2020 12:50:27 |
| User entered 'Day 7' | System | 04 Sep 2020 12:50:27 |

US3302105

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:57:13

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-09-11T07:40:54', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '8f91c43c-45b5-4307-b39f-0da8e4c027f3' | System | 11 Sep 2020 11:41:27 |
| User entered 'Yes (Y)' | System | 11 Sep 2020 11:41:27 |

US3302105

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:57:13

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-09-11T07:41:06', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '8f91c43c-45b5-4307-b39f-0da8e4c027f3' User entered '95.9' | System | 11 Sep 2020 11:41:27 |
| | System | 11 Sep 2020 11:41:27 |

US3302105

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:57:13

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-09-11T07:41:10', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '8f91c43c-45b5-4307-b39f-0da8e4c027f3' | System | 11 Sep 2020 11:41:27 |
| User entered 'No (N)' | System | 11 Sep 2020 11:41:27 |

US3302105

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:57:13

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-09-11T07:41:25', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '8f91c43c-45b5-4307-b39f-0da8e4c027f3' | System | 11 Sep 2020 11:41:27 |
| User entered '11 Sep 2020 07:41' | System | 11 Sep 2020 11:41:27 |

US3302105

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:57:13

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| User entered '10 Sep 2020 12:00' | System | 04 Sep 2020 12:50:27 |

US3302105

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:57:13

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| User entered '11 Sep 2020 11:59' | System | 04 Sep 2020 12:50:27 |

US3302105

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| Data entry locked. | System | 04 Sep 2020 12:50:27 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 04 Sep 2020 12:50:27 |

US3302105

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:57:13

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-09-04T09:00:00', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: 'eb3f6dda-2d2a-483d-99ed-3d1e93249bb4' | System | 04 Sep 2020 13:00:48 |
| User entered 'None (1)' | System | 04 Sep 2020 13:00:48 |

US3302105

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:57:13

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-09-04T09:00:08', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: 'eb3f6dda-2d2a-483d-99ed-3d1e93249bb4' User entered 'No (N)' | System | 04 Sep 2020 13:00:48 |
| | System | 04 Sep 2020 13:00:48 |

US3302105

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:57:13

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-09-04T09:00:28', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: 'eb3f6dda-2d2a-483d-99ed-3d1e93249bb4' User entered 'No (N)' | System | 04 Sep 2020 13:00:48 |
| | System | 04 Sep 2020 13:00:48 |

US3302105

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:57:13

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-09-04T09:00:31', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: 'eb3f6dda-2d2a-483d-99ed-3d1e93249bb4' | System | 04 Sep 2020 13:00:48 |
| User entered 'None (1)' | System | 04 Sep 2020 13:00:48 |

US3302105

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:57:13

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-09-04T09:00:45', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: 'eb3f6dda-2d2a-483d-99ed-3d1e93249bb4' | System | 04 Sep 2020 13:00:48 |
| User entered '04 Sep 2020 09:00' | System | 04 Sep 2020 13:00:48 |

US3302105

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:57:13

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| User entered '04 Sep 2020 08:57' | System | 04 Sep 2020 12:50:27 |

US3302105

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:57:13

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| User entered '04 Sep 2020 11:27' | System | 04 Sep 2020 12:50:27 |

US3302105

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| Data entry locked. | System | 04 Sep 2020 12:50:27 |
| User entered 'Day 1, after vaccination (at home)' | System | 04 Sep 2020 12:50:27 |

US3302105

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:57:13

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

Please select one response below

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| | | |

US3302105

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:57:13

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| | | |

US3302105

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:57:13

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) | 25 Feb 2021 19:11:02 |

US3302105

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:57:13

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

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| | | |

US3302105

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:57:13

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

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

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| | | |

US3302105

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:57:13

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

Please select one response below

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| | | |

US3302105

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:57:13

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| | | |

US3302105

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:57:13

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| User entered '04 Sep 2020 12:22' | System | 04 Sep 2020 12:50:27 |

US3302105

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:57:13

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| User entered '05 Sep 2020 11:59' | System | 04 Sep 2020 12:50:27 |

US3302105

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| Data entry locked. | System | 04 Sep 2020 12:50:27 |
| User entered 'Day 2' | System | 04 Sep 2020 12:50:27 |

US3302105

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:57:13

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-09-05T19:05:18', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: 'ab66ce3d-c56c-45fd-8442-825428fca9d4' | System | 05 Sep 2020 23:05:51 |
| User entered 'Does not interfere with activity (2)' | System | 05 Sep 2020 23:05:51 |

US3302105

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:57:13

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-09-05T19:05:22', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: 'ab66ce3d-c56c-45fd-8442-825428fca9d4' | System | 05 Sep 2020 23:05:51 |
| User entered 'No (N)' | System | 05 Sep 2020 23:05:51 |

US3302105

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:57:13

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-09-05T19:05:40', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: 'ab66ce3d-c56c-45fd-8442-825428fca9d4' | System | 05 Sep 2020 23:05:51 |
| User entered 'No (N)' | System | 05 Sep 2020 23:05:51 |

US3302105

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:57:13

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-09-05T19:05:44', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: 'ab66ce3d-c56c-45fd-8442-825428fca9d4' | System | 05 Sep 2020 23:05:51 |
| User entered 'None (1)' | System | 05 Sep 2020 23:05:51 |

US3302105

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:57:13

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-09-05T19:05:48', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: 'ab66ce3d-c56c-45fd-8442-825428fca9d4' User entered '05 Sep 2020 19:05' | System | 05 Sep 2020 23:05:51 |
| | System | 05 Sep 2020 23:05:51 |

US3302105

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:57:13

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| User entered '05 Sep 2020 12:00' | System | 04 Sep 2020 12:50:27 |

US3302105

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:57:13

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| User entered '06 Sep 2020 11:59' | System | 04 Sep 2020 12:50:27 |

US3302105

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| Data entry locked. | System | 04 Sep 2020 12:50:27 |
| User entered 'Day 3' | System | 04 Sep 2020 12:50:27 |

US3302105

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:57:13

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-09-06T22:07:38', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: 'e8eebbb7-a818-4440-b80e-fb99925c4b38' | System | 07 Sep 2020 02:07:58 |
| User entered 'Does not interfere with activity (2)' | System | 07 Sep 2020 02:07:58 |

US3302105

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:57:13

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-09-06T22:07:43', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: 'e8eebbb7-a818-4440-b80e-fb99925c4b38' User entered 'No (N)' | System | 07 Sep 2020 02:07:58 |
| | System | 07 Sep 2020 02:07:58 |

US3302105

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:57:13

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-09-06T22:07:46', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: 'e8eebbb7-a818-4440-b80e-fb99925c4b38' User entered 'No (N)' | System | 07 Sep 2020 02:07:58 |
| | System | 07 Sep 2020 02:07:58 |

US3302105

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:57:13

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-09-06T22:07:50', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: 'e8eebbb7-a818-4440-b80e-fb99925c4b38' User entered 'None (1)' | System | 07 Sep 2020 02:07:58 |
| | System | 07 Sep 2020 02:07:58 |

US3302105

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:57:13

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-09-06T22:07:53', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: 'e8eebbb7-a818-4440-b80e-fb99925c4b38' User entered '06 Sep 2020 22:07' | System | 07 Sep 2020 02:07:58 |
| | System | 07 Sep 2020 02:07:58 |

US3302105

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:57:13

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| User entered '06 Sep 2020 12:00' | System | 04 Sep 2020 12:50:27 |

US3302105

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:57:13

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| User entered '07 Sep 2020 11:59' | System | 04 Sep 2020 12:50:27 |

US3302105

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| Data entry locked. | System | 04 Sep 2020 12:50:27 |
| User entered 'Day 4' | System | 04 Sep 2020 12:50:27 |

US3302105

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:57:13

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-09-08T06:50:48', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '893e23fb-e32a-45bc-b828-7318699cc208' | System | 08 Sep 2020 10:51:07 |
| User entered 'Does not interfere with activity (2)' | System | 08 Sep 2020 10:51:07 |

US3302105

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:57:13

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-09-08T06:50:52', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '893e23fb-e32a-45bc-b828-7318699cc208' | System | 08 Sep 2020 10:51:07 |
| User entered 'No (N)' | System | 08 Sep 2020 10:51:07 |

US3302105

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:57:13

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-09-08T06:50:55', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '893e23fb-e32a-45bc-b828-7318699cc208' User entered 'No (N)' | System | 08 Sep 2020 10:51:07 |
| | System | 08 Sep 2020 10:51:07 |

US3302105

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:57:13

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-09-08T06:50:59', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '893e23fb-e32a-45bc-b828-7318699cc208' | System | 08 Sep 2020 10:51:07 |
| User entered 'None (1)' | System | 08 Sep 2020 10:51:07 |

US3302105

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:57:13

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-09-08T06:51:03', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '893e23fb-e32a-45bc-b828-7318699cc208' User entered '08 Sep 2020 06:51' | System | 08 Sep 2020 10:51:07 |
| | System | 08 Sep 2020 10:51:07 |

US3302105

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:57:13

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| User entered '07 Sep 2020 12:00' | System | 04 Sep 2020 12:50:27 |

US3302105

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:57:13

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| User entered '08 Sep 2020 11:59' | System | 04 Sep 2020 12:50:27 |

US3302105

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| Data entry locked. | System | 04 Sep 2020 12:50:27 |
| User entered 'Day 5' | System | 04 Sep 2020 12:50:27 |

US3302105

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:57:13

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

Please select one response below

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| | | |

US3302105

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:57:13

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

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| | | |

US3302105

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:57:13

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) | 25 Feb 2021 19:11:02 |
| | | |

US3302105

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:57:13

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

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| | | |

US3302105

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:57:13

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

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

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| | | |

US3302105

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:57:13

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

Please select one response below

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| | | |

US3302105

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:57:13

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| | | |

US3302105

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:57:13

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| User entered '08 Sep 2020 12:00' | System | 04 Sep 2020 12:50:27 |

US3302105

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:57:13

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| User entered '09 Sep 2020 11:59' | System | 04 Sep 2020 12:50:27 |

US3302105

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| Data entry locked. | System | 04 Sep 2020 12:50:27 |
| User entered 'Day 6' | System | 04 Sep 2020 12:50:27 |

US3302105

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:57:13

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-09-10T06:30:41', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '76b0b6fd-dd48-4828-935a-3a15eab315eb' | System | 10 Sep 2020 10:31:05 |
| User entered 'Does not interfere with activity (2)' | System | 10 Sep 2020 10:31:05 |

US3302105

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:57:13

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-09-10T06:30:45', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '76b0b6fd-dd48-4828-935a-3a15eab315eb' User entered 'No (N)' | System | 10 Sep 2020 10:31:05 |
| | System | 10 Sep 2020 10:31:05 |

US3302105

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:57:13

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-09-10T06:30:55', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '76b0b6fd-dd48-4828-935a-3a15eab315eb' User entered 'No (N)' | System | 10 Sep 2020 10:31:05 |
| | System | 10 Sep 2020 10:31:05 |

US3302105

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:57:13

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-09-10T06:30:58', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '76b0b6fd-dd48-4828-935a-3a15eab315eb' User entered 'None (1)' | System | 10 Sep 2020 10:31:05 |
| | System | 10 Sep 2020 10:31:05 |

US3302105

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:57:13

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-09-10T06:31:03', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '76b0b6fd-dd48-4828-935a-3a15eab315eb' User entered '10 Sep 2020 06:31' | System | 10 Sep 2020 10:31:05 |
| | System | 10 Sep 2020 10:31:05 |

US3302105

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:57:13

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| User entered '09 Sep 2020 12:00' | System | 04 Sep 2020 12:50:27 |

US3302105

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:57:13

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| User entered '10 Sep 2020 11:59' | System | 04 Sep 2020 12:50:27 |

US3302105

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| Data entry locked. | System | 04 Sep 2020 12:50:27 |
| User entered 'Day 7' | System | 04 Sep 2020 12:50:27 |

US3302105

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:57:13

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-09-11T07:41:32', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: 'c916103f-f289-4c44-8494-8a61812e0c0d' User entered 'None (1)' | System | 11 Sep 2020 11:41:48 |
| | System | 11 Sep 2020 11:41:48 |

US3302105

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:57:13

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-09-11T07:41:36', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: 'c916103f-f289-4c44-8494-8a61812e0c0d' User entered 'No (N)' | System | 11 Sep 2020 11:41:48 |
| | System | 11 Sep 2020 11:41:48 |

US3302105

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:57:13

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-09-11T07:41:39', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: 'c916103f-f289-4c44-8494-8a61812e0c0d' User entered 'No (N)' | System | 11 Sep 2020 11:41:48 |
| | System | 11 Sep 2020 11:41:48 |

US3302105

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:57:13

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-09-11T07:41:43', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: 'c916103f-f289-4c44-8494-8a61812e0c0d' User entered 'None (1)' | System | 11 Sep 2020 11:41:48 |
| | System | 11 Sep 2020 11:41:48 |

US3302105

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:57:13

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-09-11T07:41:46', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: 'c916103f-f289-4c44-8494-8a61812e0c0d' User entered '11 Sep 2020 07:41' | System | 11 Sep 2020 11:41:48 |
| | System | 11 Sep 2020 11:41:48 |

US3302105

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:57:13

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| User entered '10 Sep 2020 12:00' | System | 04 Sep 2020 12:50:27 |

US3302105

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:57:13

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| User entered '11 Sep 2020 11:59' | System | 04 Sep 2020 12:50:27 |

US3302105

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| Data entry locked. | System | 04 Sep 2020 12:50:27 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 04 Sep 2020 12:50:27 |

US3302105

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:57:13

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-09-04T09:00:51', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '5b4b6c04-08a1-4666-b9f4-61987d884d88' User entered 'None (0)' | System | 04 Sep 2020 13:01:20 |
| | System | 04 Sep 2020 13:01:20 |

US3302105

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:57:13

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-09-04T09:00:56', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '5b4b6c04-08a1-4666-b9f4-61987d884d88' User entered 'None (0)' | System | 04 Sep 2020 13:01:20 |
| | System | 04 Sep 2020 13:01:20 |

US3302105

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:57:13

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-09-04T09:00:59', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '5b4b6c04-08a1-4666-b9f4-61987d884d88' User entered 'None (0)' | System | 04 Sep 2020 13:01:20 |
| | System | 04 Sep 2020 13:01:20 |

US3302105

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:57:13

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-09-04T09:01:02', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '5b4b6c04-08a1-4666-b9f4-61987d884d88' User entered 'None (0)' | System | 04 Sep 2020 13:01:20 |
| | System | 04 Sep 2020 13:01:20 |

US3302105

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:57:13

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-09-04T09:01:05', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '5b4b6c04-08a1-4666-b9f4-61987d884d88' User entered 'None (0)' | System | 04 Sep 2020 13:01:20 |
| | System | 04 Sep 2020 13:01:20 |

US3302105

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:57:13

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-09-04T09:01:08', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '5b4b6c04-08a1-4666-b9f4-61987d884d88' User entered 'None (0)' | System | 04 Sep 2020 13:01:20 |
| | System | 04 Sep 2020 13:01:20 |

US3302105

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:57:13

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) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-09-04T09:01:12', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '5b4b6c04-08a1-4666-b9f4-61987d884d88' User entered 'No (N)' | System | 04 Sep 2020 13:01:20 |
| | System | 04 Sep 2020 13:01:20 |

US3302105

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:57:13

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-09-04T09:01:18', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '5b4b6c04-08a1-4666-b9f4-61987d884d88' User entered '04 Sep 2020 09:01' | System | 04 Sep 2020 13:01:20 |
| | System | 04 Sep 2020 13:01:20 |

US3302105

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:57:13

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| User entered '04 Sep 2020 08:57' | System | 04 Sep 2020 12:50:27 |

US3302105

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:57:13

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| User entered '04 Sep 2020 11:27' | System | 04 Sep 2020 12:50:27 |

US3302105

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| Data entry locked. | System | 04 Sep 2020 12:50:27 |
| User entered 'Day 1, after vaccination (at home)' | System | 04 Sep 2020 12:50:27 |

US3302105

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:57:13

HEADACHE

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| | | |

US3302105

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:57:13

FATIGUE

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| | | |

US3302105

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:57:13

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| | | |

US3302105

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:57:13

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| | | |

US3302105

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:57:13

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| | | |

US3302105

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:57:13

CHILLS

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| | | |

US3302105

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:57:13

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) | 25 Feb 2021 19:11:02 |
| | | |

US3302105

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:57:13

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| | | |

US3302105

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:57:13

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| User entered '04 Sep 2020 12:22' | System | 04 Sep 2020 12:50:27 |

US3302105

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:57:13

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| User entered '05 Sep 2020 11:59' | System | 04 Sep 2020 12:50:27 |

US3302105

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| Data entry locked. | System | 04 Sep 2020 12:50:27 |
| User entered 'Day 2' | System | 04 Sep 2020 12:50:27 |

US3302105

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:57:13

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-09-05T19:05:56', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '18fad567-2881-4b4f-9694-51f85603b554' User entered 'None (0)' | System | 05 Sep 2020 23:06:33 |
| | System | 05 Sep 2020 23:06:33 |

US3302105

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:57:13

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-09-05T19:06:03', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '18fad567-2881-4b4f-9694-51f85603b554' | System | 05 Sep 2020 23:06:33 |
| User entered 'Some interference with activity (2)' | System | 05 Sep 2020 23:06:33 |

US3302105

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:57:13

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-09-05T19:06:06', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '18fad567-2881-4b4f-9694-51f85603b554' User entered 'None (0)' | System | 05 Sep 2020 23:06:33 |
| | System | 05 Sep 2020 23:06:33 |

US3302105

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:57:13

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-09-05T19:06:11', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '18fad567-2881-4b4f-9694-51f85603b554' | System | 05 Sep 2020 23:06:33 |
| User entered 'No interference with activity (1)' | System | 05 Sep 2020 23:06:33 |

US3302105

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:57:13

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-09-05T19:06:14', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '18fad567-2881-4b4f-9694-51f85603b554' User entered 'None (0)' | System | 05 Sep 2020 23:06:33 |
| | System | 05 Sep 2020 23:06:33 |

US3302105

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:57:13

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-09-05T19:06:17', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '18fad567-2881-4b4f-9694-51f85603b554' User entered 'None (0)' | System | 05 Sep 2020 23:06:33 |
| | System | 05 Sep 2020 23:06:33 |

US3302105

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:57:13

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) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-09-05T19:06:21', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '18fad567-2881-4b4f-9694-51f85603b554' | System | 05 Sep 2020 23:06:33 |
| User entered 'No (N)' | System | 05 Sep 2020 23:06:33 |

US3302105

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:57:13

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-09-05T19:06:30', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '18fad567-2881-4b4f-9694-51f85603b554' User entered '05 Sep 2020 19:06' | System | 05 Sep 2020 23:06:33 |
| | System | 05 Sep 2020 23:06:33 |

US3302105

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:57:13

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| User entered '05 Sep 2020 12:00' | System | 04 Sep 2020 12:50:27 |

US3302105

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:57:13

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| User entered '06 Sep 2020 11:59' | System | 04 Sep 2020 12:50:27 |

US3302105

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| Data entry locked. | System | 04 Sep 2020 12:50:27 |
| User entered 'Day 3' | System | 04 Sep 2020 12:50:27 |

US3302105

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:57:13

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-09-06T22:08:00', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '66227e04-1b09-42e3-a9fe-07772f73fe15' User entered 'None (0)' | System | 07 Sep 2020 02:08:32 |
| | System | 07 Sep 2020 02:08:32 |

US3302105

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:57:13

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-09-06T22:08:05', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '66227e04-1b09-42e3-a9fe-07772f73fe15' | System | 07 Sep 2020 02:08:32 |
| User entered 'No interference with activity (1)' | System | 07 Sep 2020 02:08:32 |

US3302105

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:57:13

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-09-06T22:08:08', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '66227e04-1b09-42e3-a9fe-07772f73fe15' User entered 'None (0)' | System | 07 Sep 2020 02:08:32 |
| | System | 07 Sep 2020 02:08:32 |

US3302105

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:57:13

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-09-06T22:08:10', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '66227e04-1b09-42e3-a9fe-07772f73fe15' User entered 'None (0)' | System | 07 Sep 2020 02:08:32 |
| | System | 07 Sep 2020 02:08:32 |

US3302105

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:57:13

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-09-06T22:08:14', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '66227e04-1b09-42e3-a9fe-07772f73fe15' User entered 'None (0)' | System | 07 Sep 2020 02:08:32 |
| | System | 07 Sep 2020 02:08:32 |

US3302105

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:57:13

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-09-06T22:08:17', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '66227e04-1b09-42e3-a9fe-07772f73fe15' | System | 07 Sep 2020 02:08:32 |
| User entered 'None (0)' | System | 07 Sep 2020 02:08:32 |

US3302105

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:57:13

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) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-09-06T22:08:20', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '66227e04-1b09-42e3-a9fe-07772f73fe15' | System | 07 Sep 2020 02:08:32 |
| User entered 'No (N)' | System | 07 Sep 2020 02:08:32 |

US3302105

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:57:13

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-09-06T22:08:28', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '66227e04-1b09-42e3-a9fe-07772f73fe15' User entered '06 Sep 2020 22:08' | System | 07 Sep 2020 02:08:32 |
| | System | 07 Sep 2020 02:08:32 |

US3302105

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:57:13

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| User entered '06 Sep 2020 12:00' | System | 04 Sep 2020 12:50:27 |

US3302105

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:57:13

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| User entered '07 Sep 2020 11:59' | System | 04 Sep 2020 12:50:27 |

US3302105

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| Data entry locked. | System | 04 Sep 2020 12:50:27 |
| User entered 'Day 4' | System | 04 Sep 2020 12:50:27 |

US3302105

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:57:13

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-09-08T06:51:09', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '048695a4-04cf-48e7-841e-8c5c7723ddbb' User entered 'None (0)' | System | 08 Sep 2020 10:51:38 |
| | System | 08 Sep 2020 10:51:38 |

US3302105

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:57:13

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-09-08T06:51:12', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '048695a4-04cf-48e7-841e-8c5c7723ddbb' User entered 'None (0)' | System | 08 Sep 2020 10:51:38 |
| | System | 08 Sep 2020 10:51:38 |

US3302105

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:57:13

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-09-08T06:51:15', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '048695a4-04cf-48e7-841e-8c5c7723ddbb' User entered 'None (0)' | System | 08 Sep 2020 10:51:38 |
| | System | 08 Sep 2020 10:51:38 |

US3302105

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:57:13

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-09-08T06:51:17', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '048695a4-04cf-48e7-841e-8c5c7723ddbb' User entered 'None (0)' | System | 08 Sep 2020 10:51:38 |
| | System | 08 Sep 2020 10:51:38 |

US3302105

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:57:13

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-09-08T06:51:20', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '048695a4-04cf-48e7-841e-8c5c7723ddbb' User entered 'None (0)' | System | 08 Sep 2020 10:51:38 |
| | System | 08 Sep 2020 10:51:38 |

US3302105

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:57:13

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-09-08T06:51:22', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '048695a4-04cf-48e7-841e-8c5c7723ddbb' User entered 'None (0)' | System | 08 Sep 2020 10:51:38 |
| | System | 08 Sep 2020 10:51:38 |

US3302105

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:57:13

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) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-09-08T06:51:25', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '048695a4-04cf-48e7-841e-8c5c7723ddbb' User entered 'No (N)' | System | 08 Sep 2020 10:51:38 |
| | System | 08 Sep 2020 10:51:38 |

US3302105

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:57:13

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-09-08T06:51:32', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '048695a4-04cf-48e7-841e-8c5c7723ddbb' User entered '08 Sep 2020 06:51' | System | 08 Sep 2020 10:51:38 |
| | System | 08 Sep 2020 10:51:38 |

US3302105

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:57:13

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| User entered '07 Sep 2020 12:00' | System | 04 Sep 2020 12:50:27 |

US3302105

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:57:13

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| User entered '08 Sep 2020 11:59' | System | 04 Sep 2020 12:50:27 |

US3302105

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| Data entry locked. | System | 04 Sep 2020 12:50:27 |
| User entered 'Day 5' | System | 04 Sep 2020 12:50:27 |

US3302105

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:57:13

HEADACHE

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| | | |

US3302105

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:57:13

FATIGUE

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| | | |

US3302105

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:57:13

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| | | |

US3302105

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:57:13

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| | | |

US3302105

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:57:13

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| | | |

US3302105

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:57:13

CHILLS

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| | | |

US3302105

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:57:13

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) | 25 Feb 2021 19:11:02 |
| | | |

US3302105

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:57:13

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| | | |

US3302105

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:57:13

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| User entered '08 Sep 2020 12:00' | System | 04 Sep 2020 12:50:27 |

US3302105

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:57:13

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| User entered '09 Sep 2020 11:59' | System | 04 Sep 2020 12:50:27 |

US3302105

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| Data entry locked. | System | 04 Sep 2020 12:50:27 |
| User entered 'Day 6' | System | 04 Sep 2020 12:50:27 |

US3302105

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:57:13

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-09-10T06:31:14', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '62035bde-ca69-4935-9bae-fba0d67ea95c' User entered 'None (0)' | System | 10 Sep 2020 10:31:42 |
| | System | 10 Sep 2020 10:31:42 |

US3302105

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:57:13

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-09-10T06:31:17', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '62035bde-ca69-4935-9bae-fba0d67ea95c' User entered 'None (0)' | System | 10 Sep 2020 10:31:42 |
| | System | 10 Sep 2020 10:31:42 |

US3302105

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:57:13

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-09-10T06:31:19', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '62035bde-ca69-4935-9bae-fba0d67ea95c' User entered 'None (0)' | System | 10 Sep 2020 10:31:42 |
| | System | 10 Sep 2020 10:31:42 |

US3302105

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:57:13

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-09-10T06:31:24', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '62035bde-ca69-4935-9bae-fba0d67ea95c' User entered 'None (0)' | System | 10 Sep 2020 10:31:42 |
| | System | 10 Sep 2020 10:31:42 |

US3302105

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:57:13

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-09-10T06:31:28', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '62035bde-ca69-4935-9bae-fba0d67ea95c' User entered 'None (0)' | System | 10 Sep 2020 10:31:42 |
| | System | 10 Sep 2020 10:31:42 |

US3302105

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:57:13

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-09-10T06:31:30', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '62035bde-ca69-4935-9bae-fba0d67ea95c' User entered 'None (0)' | System | 10 Sep 2020 10:31:42 |
| | System | 10 Sep 2020 10:31:42 |

US3302105

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:57:13

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) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-09-10T06:31:35', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '62035bde-ca69-4935-9bae-fba0d67ea95c' User entered 'No (N)' | System | 10 Sep 2020 10:31:42 |
| | System | 10 Sep 2020 10:31:42 |

US3302105

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:57:13

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-09-10T06:31:38', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '62035bde-ca69-4935-9bae-fba0d67ea95c' User entered '10 Sep 2020 06:31' | System | 10 Sep 2020 10:31:42 |
| | System | 10 Sep 2020 10:31:42 |

US3302105

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:57:13

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| User entered '09 Sep 2020 12:00' | System | 04 Sep 2020 12:50:27 |

US3302105

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:57:13

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| User entered '10 Sep 2020 11:59' | System | 04 Sep 2020 12:50:27 |

US3302105

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| Data entry locked. | System | 04 Sep 2020 12:50:27 |
| User entered 'Day 7' | System | 04 Sep 2020 12:50:27 |

US3302105

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:57:13

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-09-11T07:41:58', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: 'a40236b3-3020-4146-8d31-89c7be7e8157' User entered 'None (0)' | System | 11 Sep 2020 11:42:23 |
| | System | 11 Sep 2020 11:42:23 |

US3302105

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:57:13

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-09-11T07:42:01', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: 'a40236b3-3020-4146-8d31-89c7be7e8157' User entered 'None (0)' | System | 11 Sep 2020 11:42:23 |
| | System | 11 Sep 2020 11:42:23 |

US3302105

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:57:13

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-09-11T07:42:03', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: 'a40236b3-3020-4146-8d31-89c7be7e8157' User entered 'None (0)' | System | 11 Sep 2020 11:42:23 |
| | System | 11 Sep 2020 11:42:23 |

US3302105

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:57:13

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-09-11T07:42:09', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: 'a40236b3-3020-4146-8d31-89c7be7e8157' User entered 'None (0)' | System | 11 Sep 2020 11:42:23 |
| | System | 11 Sep 2020 11:42:23 |

US3302105

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:57:13

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-09-11T07:42:12', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: 'a40236b3-3020-4146-8d31-89c7be7e8157' User entered 'None (0)' | System | 11 Sep 2020 11:42:23 |
| | System | 11 Sep 2020 11:42:23 |

US3302105

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:57:13

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-09-11T07:42:15', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: 'a40236b3-3020-4146-8d31-89c7be7e8157' User entered 'None (0)' | System | 11 Sep 2020 11:42:23 |
| | System | 11 Sep 2020 11:42:23 |

US3302105

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:57:13

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) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-09-11T07:42:18', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: 'a40236b3-3020-4146-8d31-89c7be7e8157' | System | 11 Sep 2020 11:42:23 |
| User entered 'No (N)' | System | 11 Sep 2020 11:42:23 |

US3302105

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:57:13

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-09-11T07:42:21', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: 'a40236b3-3020-4146-8d31-89c7be7e8157' | System | 11 Sep 2020 11:42:23 |
| User entered '11 Sep 2020 07:42' | System | 11 Sep 2020 11:42:23 |

US3302105

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:57:13

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| User entered '10 Sep 2020 12:00' | System | 04 Sep 2020 12:50:27 |

US3302105

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:57:13

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| User entered '11 Sep 2020 11:59' | System | 04 Sep 2020 12:50:27 |

US3302105

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:57:13

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:40 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:03:00 |
| User entered 'Yes (Y)' | (b) (4) Wendy Taylor (b) (4) | 11 Sep 2020 20:25:36 |

US3302105

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:57:13

Date of Contact or Contact Attempt (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:40 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:03:00 |
| User entered '11 Sep 2020' | (b) (4) Wendy Taylor (b) (4) | 11 Sep 2020 20:25:36 |

US3302105

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:57:13

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:40 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:03:00 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4) Wendy Taylor (b) (4) | 11 Sep 2020 20:25:36 |

US3302105

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:57:13

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:40 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:03:00 |
| User entered empty. | (b) (4) Wendy Taylor (b) (4) | 11 Sep 2020 20:25:36 |

US3302105

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:57:13

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:40 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:03:00 |
| User entered 'Yes (Y)' | (b) (4) Wendy Taylor (b) (4) | 11 Sep 2020 20:25:45 |

US3302105

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:57:13

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:40 |
| User entered 'I' | System | 11 Sep 2020 20:25:45 |

US3302105

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:57:13

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:40 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:03:00 |
| User entered 'Yes (Y)' | (b) (4) Wendy Taylor (b) (4) | 18 Sep 2020 17:28:20 |

US3302105

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:57:13

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:40 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:03:00 |
| User entered '18 Sep 2020' | (b) (4) Wendy Taylor (b) (4) | 18 Sep 2020 17:28:20 |

US3302105

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:57:13

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:40 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:03:00 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4) Wendy Taylor (b) (4) | 18 Sep 2020 17:28:20 |

US3302105

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:57:13

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:40 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:03:00 |
| User entered empty. | (b) (4) Wendy Taylor (b) (4) | 18 Sep 2020 17:28:20 |

US3302105

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:57:13

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:40 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:03:00 |
| User entered 'Yes (Y)' | (b) (4) Wendy Taylor (b) (4) | 18 Sep 2020 17:28:24 |

US3302105

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:57:13

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:40 |
| User entered 'I' | System | 18 Sep 2020 17:28:24 |

US3302105

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:57:13

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:40 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:03:00 |
| User entered 'Yes (Y)' | (b) (4) Wendy Taylor (b) (4) | 25 Sep 2020 18:06:40 |

US3302105

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:57:13

Date of Contact or Contact Attempt (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:40 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:03:00 |
| User entered '25 Sep 2020' | Wendy Taylor (b) (4) | 25 Sep 2020 18:06:40 |

US3302105

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:57:13

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:40 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:03:00 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4) Wendy Taylor (b) (4) | 25 Sep 2020 18:06:40 |

US3302105

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:57:13

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:40 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:03:00 |
| User entered empty. | (b) (4) Wendy Taylor (b) (4) | 25 Sep 2020 18:06:40 |

US3302105

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:57:13

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:40 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:03:00 |
| User entered 'Yes (Y)' | (b) (4) Wendy Taylor (b) (4) | 25 Sep 2020 18:06:43 |

US3302105

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:57:13

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:40 |
| User entered 'I' | System | 25 Sep 2020 18:06:43 |

US3302105

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:57:13

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:57 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:05:00 |
| User entered 'Yes (Y)' | (b) (4) Brittany Belcher (b) (4) | 06 Oct 2020 21:31:06 |

US3302105

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:57:13

Visit date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:57 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:05:00 |
| User entered '06 Oct 2020' reason for change: Data Entry Error | (b) (4) Brittany Belcher (b) (4) | 04 Nov 2020 18:24:04 |
| User entered '6 Oct 2020' | Brittany Belcher (b) (4) | 06 Oct 2020 21:31:06 |

US3302105

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:57:13

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

| Audit | User | Time (GMT) |
|--------------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:57 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:05:00 |
| User entered 'Clinic (Clinic)' | (b) (4) Brittany Belcher (b) (4) | 06 Oct 2020 21:31:06 |

US3302105

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:57:13

[Folder OID](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:57 |
| User entered 'VISIT3' | System | 06 Oct 2020 21:31:06 |

US3302105

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:57:13

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:57 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:05:00 |
| User entered 'Yes (Y)' | (b) (4) Brittany Belcher (b) (4) | 06 Oct 2020 21:31:23 |

US3302105

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:57:13

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:57 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:05:00 |
| User entered '06 Oct 2020' reason for change: Data Entry Error | (b) (4) | |
| | Brittany Belcher (b) (4) | 04 Nov 2020 18:24:08 |
| User entered '6 Oct 2020' | (b) (4) | 06 Oct 2020 21:31:23 |

US3302105

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:57:13

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

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:57 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:05:00 |
| User entered '17:20' | (b) (4) Brittany Belcher (b) (4) | 06 Oct 2020 21:31:23 |

US3302105

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:57:13

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:57 |
| User entered '06 Oct 2020 17:20' | System | 04 Nov 2020 18:24:08 |
| User entered '6 Oct 2020 17:20' | System | 06 Oct 2020 21:31:23 |

US3302105

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:57:13

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:57 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:05:00 |
| User entered '98.6' F | (b) (4) Brittany Belcher (b) (4) | 06 Oct 2020 21:31:23 |

US3302105

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:57:13

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:57 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:05:00 |
| User entered 'Oral (Oral)' | (b) (4) Brittany Belcher (b) (4) | 06 Oct 2020 21:31:23 |

US3302105

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:57:13

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:57 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:05:00 |
| User entered empty. | (b) (4) Brittany Belcher (b) (4) | 06 Oct 2020 21:31:23 |

US3302105

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:57:13

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:57 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:05:00 |
| User entered '66' | (b) (4) Brittany Belcher (b) (4) | 06 Oct 2020 21:31:23 |

US3302105

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:57:13

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:57 |
| User entered 'bpm' | System | 06 Oct 2020 21:31:23 |

US3302105

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:57:13

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

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:57 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:05:00 |
| User entered '18' | (b) (4) Brittany Belcher (b) (4) | 06 Oct 2020 21:31:23 |

US3302105

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:57:13

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:57 |
| User entered 'breaths/min' | System | 06 Oct 2020 21:31:23 |

US3302105

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:57:13

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:57 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:05:00 |
| User entered '155' | (b) (4) Brittany Belcher (b) (4) | 06 Oct 2020 21:31:23 |

US3302105

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:57:13

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:57 |
| User entered 'mmHg' | System | 06 Oct 2020 21:31:23 |

US3302105

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:57:13

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:57 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:05:00 |
| User entered '80' | (b) (4) Brittany Belcher (b) (4) | 06 Oct 2020 21:31:23 |

US3302105

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:57:13

Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:57 |
| User entered 'mmHg' | System | 06 Oct 2020 21:31:23 |

US3302105

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:57:13

[Height \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:57 |

US3302105

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:57:13

Weight (derived)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:57 |

US3302105

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:57:13

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:57 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:05:00 |
| User entered 'Yes (Y)' | (b) (4) Brittany Belcher (b) (4) | 06 Oct 2020 21:31:28 |

US3302105

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:57:13

Date of examination (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:57 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:05:00 |
| User entered '06 Oct 2020' reason for change: Data Entry Error | (b) (4) | |
| | Brittany Belcher (b) (4) | 04 Nov 2020 18:24:13 |
| User entered '6 Oct 2020' | (b) (4) | 06 Oct 2020 21:31:28 |

US3302105

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:57:13

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:57 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:05:00 |
| User entered 'Yes (Y)' | (b) (4) Brittany Belcher (b) (4) | 06 Oct 2020 21:31:36 |

US3302105

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:57:13

Collection date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:57 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:05:00 |
| User closed query 'Per GCL Lab Recon: Sample dated 06Oct2020 is reported under Visit3 Day57 visit in EDC, however the Sample dated 07Oct2020 is recorded under Visit3 Day57 visit in PPD Central lab. Please review and confirm the correct date.' (Site from DM). | (b) (4), (b) (6) | 25 Nov 2020 20:54:58 |
| Query 'Per GCL Lab Recon: Sample dated 06Oct2020 is reported under Visit3 Day57 visit in EDC, however the Sample dated 07Oct2020 is recorded under Visit3 Day57 visit in PPD Central lab. Please review and confirm the correct date.' answered with 'entered is the correct date' (Site from DM). | brittany cooksey (b) (4) | 13 Nov 2020 18:58:21 |
| User opened query 'Per GCL Lab Recon: Sample dated 06Oct2020 is reported under Visit3 Day57 visit in EDC, however the Sample dated 07Oct2020 is recorded under Visit3 Day57 visit in PPD Central lab. Please review and confirm the correct date.' (Site from DM). | (b) (4), (b) (6) | 10 Nov 2020 20:26:02 |
| User entered '06 Oct 2020' reason for change: Data Entry Error | Brittany Belcher (b) (4) | 04 Nov 2020 18:24:17 |
| User entered '6 Oct 2020' | Brittany Belcher (b) (4) | 06 Oct 2020 21:31:36 |

US3302105

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:57:13

Collection time (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:57 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:05:00 |
| User entered '17:22' | (b) (4) Brittany Belcher (b) (4) | 06 Oct 2020 21:31:36 |

US3302105

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:57:13

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:57 |
| User entered '06 Oct 2020 17:22' | System | 04 Nov 2020 18:24:17 |
| User entered '6 Oct 2020 17:22' | System | 06 Oct 2020 21:31:36 |

US3302105

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:57:13

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:57 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:05:00 |
| User entered 'Yes (Y)' | (b) (4) Brittany Belcher (b) (4) | 06 Oct 2020 21:31:39 |

US3302105

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:57:13

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:57 |
| User entered 'I' | System | 06 Oct 2020 21:31:39 |

US3302105

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| Data entry locked. | System | 07 Aug 2020 20:36:16 |
| User entered 'Day 64' | System | 07 Aug 2020 20:36:16 |

US3302105

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-10-08T18:19:44', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '530dc0e2-c0cd-42b1-aa78-369674806530' User entered 'No (N)' | System | 08 Oct 2020 22:20:02 |
| | System | 08 Oct 2020 22:20:02 |

US3302105

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-10-08T18:19:52', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '530dc0e2-c0cd-42b1-aa78-369674806530' User entered 'No (N)' | System | 08 Oct 2020 22:20:02 |
| | System | 08 Oct 2020 22:20:02 |

US3302105

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-10-08T18:19:59', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '530dc0e2-c0cd-42b1-aa78-369674806530' User entered '08 Oct 2020 18:19:59' | System | 08 Oct 2020 22:20:02 |
| | System | 08 Oct 2020 22:20:02 |

US3302105

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| Data entry locked. | System | 07 Aug 2020 20:36:16 |
| User entered '07 Oct 2020 00:01' | System | 07 Aug 2020 20:36:16 |

US3302105

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| Data entry locked. | System | 07 Aug 2020 20:36:16 |
| User entered '11 Oct 2020 23:59' | System | 07 Aug 2020 20:36:16 |

US3302105

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| Data entry locked. | System | 07 Aug 2020 20:36:16 |
| User entered 'Day 71' | System | 07 Aug 2020 20:36:16 |

US3302105

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-10-16T11:27:57', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '8f1a9bed-0401-470c-bed7-3f46a85e8ed3' User entered 'Yes (Y)' | System | 16 Oct 2020 15:29:19 |
| | System | 16 Oct 2020 15:29:19 |

US3302105

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-10-16T11:28:01', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '8f1a9bed-0401-470c-bed7-3f46a85e8ed3' | System | 16 Oct 2020 15:29:19 |
| User entered 'No (N)' | System | 16 Oct 2020 15:29:19 |

US3302105

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-10-16T11:28:14', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '8f1a9bed-0401-470c-bed7-3f46a85e8ed3' User entered 'Yes (Y)' | System | 16 Oct 2020 15:29:19 |
| | System | 16 Oct 2020 15:29:19 |

US3302105

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

Fever (Temperature \geq 100.4°F/38°C)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-10-16T11:28:51', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '8f1a9bed-0401-470c-bed7-3f46a85e8ed3' User entered '0' | System | 16 Oct 2020 15:29:19 |
| | System | 16 Oct 2020 15:29:19 |

US3302105

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Chills](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-10-16T11:28:51', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '8f1a9bed-0401-470c-bed7-3f46a85e8ed3' User entered '0' | System | 16 Oct 2020 15:29:19 |
| | System | 16 Oct 2020 15:29:19 |

US3302105

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Cough](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-10-16T11:28:51', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '8f1a9bed-0401-470c-bed7-3f46a85e8ed3' User entered '0' | System | 16 Oct 2020 15:29:19 |
| | System | 16 Oct 2020 15:29:19 |

US3302105

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Shortness of breath](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-10-16T11:28:51', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '8f1a9bed-0401-470c-bed7-3f46a85e8ed3' User entered '0' | System | 16 Oct 2020 15:29:19 |
| | System | 16 Oct 2020 15:29:19 |

US3302105

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Difficulty breathing](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-10-16T11:28:51', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '8f1a9bed-0401-470c-bed7-3f46a85e8ed3' User entered '0' | System | 16 Oct 2020 15:29:19 |
| | System | 16 Oct 2020 15:29:19 |

US3302105

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Fatigue](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-10-16T11:28:51', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '8f1a9bed-0401-470c-bed7-3f46a85e8ed3' User entered '0' | System | 16 Oct 2020 15:29:19 |
| | System | 16 Oct 2020 15:29:19 |

US3302105

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Muscle aches](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-10-16T11:28:51', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '8f1a9bed-0401-470c-bed7-3f46a85e8ed3' User entered '0' | System | 16 Oct 2020 15:29:19 |
| | System | 16 Oct 2020 15:29:19 |

US3302105

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Body aches](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-10-16T11:28:51', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '8f1a9bed-0401-470c-bed7-3f46a85e8ed3' User entered '0' | System | 16 Oct 2020 15:29:19 |
| | System | 16 Oct 2020 15:29:19 |

US3302105

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Headache](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-10-16T11:28:51', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '8f1a9bed-0401-470c-bed7-3f46a85e8ed3' User entered '0' | System | 16 Oct 2020 15:29:19 |
| | System | 16 Oct 2020 15:29:19 |

US3302105

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[New loss of taste](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-10-16T11:28:51', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '8f1a9bed-0401-470c-bed7-3f46a85e8ed3' User entered '0' | System | 16 Oct 2020 15:29:19 |
| | System | 16 Oct 2020 15:29:19 |

US3302105

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[New loss of smell](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-10-16T11:28:51', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '8f1a9bed-0401-470c-bed7-3f46a85e8ed3' User entered '0' | System | 16 Oct 2020 15:29:19 |
| | System | 16 Oct 2020 15:29:19 |

US3302105

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Sore throat](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-10-16T11:28:51', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '8f1a9bed-0401-470c-bed7-3f46a85e8ed3' User entered '0' | System | 16 Oct 2020 15:29:19 |
| | System | 16 Oct 2020 15:29:19 |

US3302105

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Congestion](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-10-16T11:28:51', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '8f1a9bed-0401-470c-bed7-3f46a85e8ed3' User entered '0' | System | 16 Oct 2020 15:29:19 |
| | System | 16 Oct 2020 15:29:19 |

US3302105

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Runny nose](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-10-16T11:28:51', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '8f1a9bed-0401-470c-bed7-3f46a85e8ed3' User entered '0' | System | 16 Oct 2020 15:29:19 |
| | System | 16 Oct 2020 15:29:19 |

US3302105

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Nausea](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-10-16T11:28:51', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '8f1a9bed-0401-470c-bed7-3f46a85e8ed3' User entered '1' | System | 16 Oct 2020 15:29:19 |
| | System | 16 Oct 2020 15:29:19 |

US3302105

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Vomiting](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-10-16T11:28:51', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '8f1a9bed-0401-470c-bed7-3f46a85e8ed3' User entered '1' | System | 16 Oct 2020 15:29:19 |
| | System | 16 Oct 2020 15:29:19 |

US3302105

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Diarrhea](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-10-16T11:28:51', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '8f1a9bed-0401-470c-bed7-3f46a85e8ed3' User entered '1' | System | 16 Oct 2020 15:29:19 |
| | System | 16 Oct 2020 15:29:19 |

US3302105

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-10-16T11:28:57', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '8f1a9bed-0401-470c-bed7-3f46a85e8ed3' | System | 16 Oct 2020 15:29:19 |
| User entered 'I confirm I have read this message and will call the study clinic immediately (9)' | System | 16 Oct 2020 15:29:19 |

US3302105

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-10-16T11:29:04', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '8f1a9bed-0401-470c-bed7-3f46a85e8ed3' User entered 'No (N)' | System | 16 Oct 2020 15:29:19 |
| | System | 16 Oct 2020 15:29:19 |

US3302105

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-10-16T11:29:08', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '8f1a9bed-0401-470c-bed7-3f46a85e8ed3' User entered '16 Oct 2020 11:29:08' | System | 16 Oct 2020 15:29:19 |
| | System | 16 Oct 2020 15:29:19 |

US3302105

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| Data entry locked. | System | 07 Aug 2020 20:36:16 |
| User entered '14 Oct 2020 00:01' | System | 07 Aug 2020 20:36:16 |

US3302105

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| Data entry locked. | System | 07 Aug 2020 20:36:16 |
| User entered '18 Oct 2020 23:59' | System | 07 Aug 2020 20:36:16 |

US3302105

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| Data entry locked. | System | 07 Aug 2020 20:36:16 |
| User entered 'Day 78' | System | 07 Aug 2020 20:36:16 |

US3302105

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-10-23T15:16:40', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: 'aa68b298-f819-4563-a65c-050658414c3b' User entered 'No (N)' | System | 23 Oct 2020 19:16:55 |
| | System | 23 Oct 2020 19:16:55 |

US3302105

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-10-23T15:16:44', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: 'aa68b298-f819-4563-a65c-050658414c3b' User entered 'No (N)' | System | 23 Oct 2020 19:16:55 |
| | System | 23 Oct 2020 19:16:55 |

US3302105

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-10-23T15:16:51', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: 'aa68b298-f819-4563-a65c-050658414c3b' User entered '23 Oct 2020 15:16:51' | System | 23 Oct 2020 19:16:55 |
| | System | 23 Oct 2020 19:16:55 |

US3302105

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| Data entry locked. | System | 07 Aug 2020 20:36:16 |
| User entered '21 Oct 2020 00:01' | System | 07 Aug 2020 20:36:16 |

US3302105

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| Data entry locked. | System | 07 Aug 2020 20:36:16 |
| User entered '25 Oct 2020 23:59' | System | 07 Aug 2020 20:36:16 |

US3302105

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| Data entry locked. | System | 07 Aug 2020 20:36:16 |
| User entered 'Day 92' | System | 07 Aug 2020 20:36:16 |

US3302105

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-11-08T22:21:10', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '61da9e9d-e247-4123-b222-3e4581e0f79c' | System | 09 Nov 2020 03:21:22 |
| User entered 'No (N)' | System | 09 Nov 2020 03:21:22 |

US3302105

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-11-08T22:21:14', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '61da9e9d-e247-4123-b222-3e4581e0f79c' | System | 09 Nov 2020 03:21:22 |
| User entered 'No (N)' | System | 09 Nov 2020 03:21:22 |

US3302105

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-11-08T22:21:20', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '61da9e9d-e247-4123-b222-3e4581e0f79c' User entered '08 Nov 2020 22:21:20' | System | 09 Nov 2020 03:21:22 |
| | System | 09 Nov 2020 03:21:22 |

US3302105

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| Data entry locked. | System | 07 Aug 2020 20:36:16 |
| User entered '04 Nov 2020 00:01' | System | 07 Aug 2020 20:36:16 |

US3302105

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| Data entry locked. | System | 07 Aug 2020 20:36:16 |
| User entered '08 Nov 2020 23:59' | System | 07 Aug 2020 20:36:16 |

US3302105

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| Data entry locked. | System | 07 Aug 2020 20:36:16 |
| User entered 'Day 99' | System | 07 Aug 2020 20:36:16 |

US3302105

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-11-12T12:16:25', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '7c355b66-bae9-4a6f-bba4-c5e1fe1b4ab6' | System | 12 Nov 2020 17:16:41 |
| User entered 'No (N)' | System | 12 Nov 2020 17:16:41 |

US3302105

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-11-12T12:16:31', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '7c355b66-bae9-4a6f-bba4-c5e1fe1b4ab6' | System | 12 Nov 2020 17:16:41 |
| User entered 'No (N)' | System | 12 Nov 2020 17:16:41 |

US3302105

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-11-12T12:16:38', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '7c355b66-bae9-4a6f-bba4-c5e1fe1b4ab6' User entered '12 Nov 2020 12:16:38' | System | 12 Nov 2020 17:16:41 |
| | System | 12 Nov 2020 17:16:41 |

US3302105

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| Data entry locked. | System | 07 Aug 2020 20:36:16 |
| User entered '11 Nov 2020 00:01' | System | 07 Aug 2020 20:36:16 |

US3302105

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 19:11:02 |
| Data entry locked. | System | 07 Aug 2020 20:36:16 |
| User entered '15 Nov 2020 23:59' | System | 07 Aug 2020 20:36:16 |

US3302105

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 04:55:32 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 16:14:43 |
| Data entry locked. | System | 07 Aug 2020 20:36:16 |
| User entered 'Day 106' | System | 07 Aug 2020 20:36:16 |

US3302105

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[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) | 24 Apr 2021 04:55:32 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Have you been exposed to someone with 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) | 24 Apr 2021 04:55:32 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 04:55:32 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 04:55:32 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

Fever (Temperature \geq 100.4°F/38°C)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 04:55:32 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Chills](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 04:55:32 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Cough](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 04:55:32 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Shortness of breath](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 04:55:32 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Difficulty breathing](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 04:55:32 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Fatigue](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 04:55:32 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Muscle aches](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 04:55:32 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Body aches](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 04:55:32 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Headache](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 04:55:32 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[New loss of taste](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 04:55:32 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[New loss of smell](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 04:55:32 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Sore throat](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 04:55:32 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Congestion](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 04:55:32 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Runny nose](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 04:55:32 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Nausea](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 04:55:32 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Vomiting](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 04:55:32 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Diarrhea](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 04:55:32 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 04:55:32 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 04:55:32 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 04:55:32 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 04:55:32 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 04:55:32 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 16:14:43 |
| Data entry locked. | System | 07 Aug 2020 20:36:16 |
| User entered '18 Nov 2020 00:01' | System | 07 Aug 2020 20:36:16 |

US3302105

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 04:55:32 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 16:14:43 |
| Data entry locked. | System | 07 Aug 2020 20:36:16 |
| User entered '22 Nov 2020 23:59' | System | 07 Aug 2020 20:36:16 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered 'Day 103' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[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 (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-11-19T21:55:18', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: 'a19aa725-65e8-4dde-afb7-c9fb72f59f2e' User entered 'No (N)' | System | 20 Nov 2020 02:55:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

Have you been exposed to someone with 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 (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-11-19T21:55:26', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: 'a19aa725-65e8-4dde-afb7-c9fb72f59f2e' User entered 'No (N)' | System | 20 Nov 2020 02:55:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-11-19T21:55:40', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: 'a19aa725-65e8-4dde-afb7-c9fb72f59f2e' User entered '19 Nov 2020 21:55:40' | System | 20 Nov 2020 02:55:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '15 Nov 2020 00:01' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '19 Nov 2020 23:59' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered 'Day 110' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '22 Nov 2020 00:01' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '26 Nov 2020 23:59' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered 'Day 117' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[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 (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-12-03T16:13:18', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: 'd0de0970-2fd4-46b2-9f14-99b53e3a7bb9' User entered 'No (N)' | System | 03 Dec 2020 21:14:19 |
| | System | 03 Dec 2020 21:14:19 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

Have you been exposed to someone with 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 (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-12-03T16:14:02', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: 'd0de0970-2fd4-46b2-9f14-99b53e3a7bb9' User entered 'No (N)' | System | 03 Dec 2020 21:14:19 |
| | System | 03 Dec 2020 21:14:19 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-12-03T16:14:15', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: 'd0de0970-2fd4-46b2-9f14-99b53e3a7bb9' User entered '03 Dec 2020 16:14:15' | System | 03 Dec 2020 21:14:19 |
| | System | 03 Dec 2020 21:14:19 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '29 Nov 2020 00:01' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '03 Dec 2020 23:59' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered 'Day 124' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[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 (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-12-09T20:34:10', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '3f7665ea-e8a2-4e04-ad8a-f9af4be0b872' User entered 'No (N)' | System | 10 Dec 2020 01:34:46 |
| | System | 10 Dec 2020 01:34:46 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

Have you been exposed to someone with 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 (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-12-09T20:34:26', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '3f7665ea-e8a2-4e04-ad8a-f9af4be0b872' User entered 'No (N)' | System | 10 Dec 2020 01:34:46 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-12-09T20:34:44', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '3f7665ea-e8a2-4e04-ad8a-f9af4be0b872' User entered '09 Dec 2020 20:34:44' | System | 10 Dec 2020 01:34:46 |
| | System | 10 Dec 2020 01:34:46 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '06 Dec 2020 00:01' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '10 Dec 2020 23:59' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered 'Day 131' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[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 (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-12-16T16:02:48', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '5f46e9ec-9d1a-4913-abd6-da51af344a27' | System | 16 Dec 2020 21:03:07 |
| User entered 'No (N)' | System | 16 Dec 2020 21:03:07 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

Have you been exposed to someone with 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 (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-12-16T16:02:56', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '5f46e9ec-9d1a-4913-abd6-da51af344a27' | System | 16 Dec 2020 21:03:07 |
| User entered 'No (N)' | System | 16 Dec 2020 21:03:07 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-12-16T16:03:01', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '5f46e9ec-9d1a-4913-abd6-da51af344a27' User entered '16 Dec 2020 16:03:01' | System | 16 Dec 2020 21:03:07 |
| | System | 16 Dec 2020 21:03:07 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '13 Dec 2020 00:01' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '17 Dec 2020 23:59' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered 'Day 138' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[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 (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-12-21T09:17:48', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '6742ff4f-99f6-4746-8a36-1b6d2188c853' | System | 21 Dec 2020 14:18:16 |
| User entered 'No (N)' | System | 21 Dec 2020 14:18:16 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

Have you been exposed to someone with 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 (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-12-21T09:18:07', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '6742ff4f-99f6-4746-8a36-1b6d2188c853' | System | 21 Dec 2020 14:18:16 |
| User entered 'No (N)' | System | 21 Dec 2020 14:18:16 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-12-21T09:18:11', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '6742ff4f-99f6-4746-8a36-1b6d2188c853' User entered '21 Dec 2020 09:18:11' | System | 21 Dec 2020 14:18:16 |
| | System | 21 Dec 2020 14:18:16 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '20 Dec 2020 00:01' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '24 Dec 2020 23:59' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered 'Day 145' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[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 (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-12-28T11:18:31', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '0e06ed60-838a-4fff-8203-e3036fe5eb6e' User entered 'No (N)' | System | 28 Dec 2020 16:18:49 |
| | System | 28 Dec 2020 16:18:49 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

Have you been exposed to someone with 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 (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-12-28T11:18:39', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '0e06ed60-838a-4fff-8203-e3036fe5eb6e' User entered 'No (N)' | System | 28 Dec 2020 16:18:49 |
| | System | 28 Dec 2020 16:18:49 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2020-12-28T11:18:45', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '0e06ed60-838a-4fff-8203-e3036fe5eb6e' User entered '28 Dec 2020 11:18:45' | System | 28 Dec 2020 16:18:49 |
| | System | 28 Dec 2020 16:18:49 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '27 Dec 2020 00:01' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '31 Dec 2020 23:59' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered 'Day 152' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[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 (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2021-01-04T09:31:50', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '6fbbfe5c-c626-454d-a8bc-fbec794ff2f8' | System | 04 Jan 2021 14:31:58 |
| User entered 'No (N)' | System | 04 Jan 2021 14:31:58 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

Have you been exposed to someone with 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 (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2021-01-04T09:31:52', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '6fbbfe5c-c626-454d-a8bc-fbec794ff2f8' | System | 04 Jan 2021 14:31:58 |
| User entered 'No (N)' | System | 04 Jan 2021 14:31:58 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2021-01-04T09:31:56', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '6fbbfe5c-c626-454d-a8bc-fbec794ff2f8' | System | 04 Jan 2021 14:31:58 |
| User entered '04 Jan 2021 09:31:56' | System | 04 Jan 2021 14:31:58 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '03 Jan 2021 00:01' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '07 Jan 2021 23:59' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered 'Day 159' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[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 (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2021-01-12T12:58:51', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: 'a6c8cc63-9b22-43dd-98e0-943f59d31f8e' User entered 'No (N)' | System | 12 Jan 2021 17:59:04 |
| | System | 12 Jan 2021 17:59:04 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

Have you been exposed to someone with 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 (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2021-01-12T12:58:55', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: 'a6c8cc63-9b22-43dd-98e0-943f59d31f8e' User entered 'No (N)' | System | 12 Jan 2021 17:59:04 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2021-01-12T12:59:02', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: 'a6c8cc63-9b22-43dd-98e0-943f59d31f8e' User entered '12 Jan 2021 12:59:02' | System | 12 Jan 2021 17:59:04 |
| | System | 12 Jan 2021 17:59:04 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '10 Jan 2021 00:01' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '14 Jan 2021 23:59' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered 'Day 166' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[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 (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2021-01-18T09:22:52', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '1c9d2af4-fc6b-44cd-942c-f389eb3bd173' | System | 18 Jan 2021 14:23:40 |
| User entered 'Yes (Y)' | System | 18 Jan 2021 14:23:40 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Have you been exposed to someone with 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 (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2021-01-18T09:22:58', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '1c9d2af4-fc6b-44cd-942c-f389eb3bd173' | System | 18 Jan 2021 14:23:40 |
| User entered 'No (N)' | System | 18 Jan 2021 14:23:40 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2021-01-18T09:23:06', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '1c9d2af4-fc6b-44cd-942c-f389eb3bd173' | System | 18 Jan 2021 14:23:40 |
| User entered 'No (N)' | System | 18 Jan 2021 14:23:40 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2021-01-18T09:23:14', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '1c9d2af4-fc6b-44cd-942c-f389eb3bd173' | System | 18 Jan 2021 14:23:40 |
| User entered 'No (N)' | System | 18 Jan 2021 14:23:40 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2021-01-18T09:23:37', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '1c9d2af4-fc6b-44cd-942c-f389eb3bd173' | System | 18 Jan 2021 14:23:40 |
| User entered '18 Jan 2021 09:23:37' | System | 18 Jan 2021 14:23:40 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '17 Jan 2021 00:01' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '21 Jan 2021 23:59' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered 'Day 173' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[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 (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2021-01-27T06:39:59', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: 'b3ebff6c-d664-40aa-a4b5-5bd2136ced43' | System | 27 Jan 2021 11:40:48 |
| User entered 'No (N)' | System | 27 Jan 2021 11:40:48 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

Have you been exposed to someone with 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 (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2021-01-27T06:40:10', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: 'b3ebff6c-d664-40aa-a4b5-5bd2136ced43' | System | 27 Jan 2021 11:40:48 |
| User entered 'Yes (Y)' | System | 27 Jan 2021 11:40:48 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2021-01-27T06:40:25', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: 'b3ebff6c-d664-40aa-a4b5-5bd2136ced43' | System | 27 Jan 2021 11:40:48 |
| User entered 'I confirm I have read this message and will call the study clinic immediately (9)' | System | 27 Jan 2021 11:40:48 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2021-01-27T06:40:36', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: 'b3ebff6c-d664-40aa-a4b5-5bd2136ced43' | System | 27 Jan 2021 11:40:48 |
| User entered '27 Jan 2021 06:40:36' | System | 27 Jan 2021 11:40:48 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '24 Jan 2021 00:01' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '28 Jan 2021 23:59' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered 'Day 180' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[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 (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2021-02-01T08:52:24', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: 'df75e4e8-90f2-4b5d-a273-a082b819d4ff' User entered 'No (N)' | System | 01 Feb 2021 13:52:35 |
| | System | 01 Feb 2021 13:52:35 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

Have you been exposed to someone with 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 (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2021-02-01T08:52:28', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: 'df75e4e8-90f2-4b5d-a273-a082b819d4ff' User entered 'No (N)' | System | 01 Feb 2021 13:52:35 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2021-02-01T08:52:32', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: 'df75e4e8-90f2-4b5d-a273-a082b819d4ff' User entered '01 Feb 2021 08:52:32' | System | 01 Feb 2021 13:52:35 |
| | System | 01 Feb 2021 13:52:35 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '31 Jan 2021 00:01' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '04 Feb 2021 23:59' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered 'Day 187' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[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 (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2021-02-09T09:42:55', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '78b69b32-db79-47a6-8f1f-987e4900de73' User entered 'No (N)' | System | 09 Feb 2021 14:43:13 |
| | System | 09 Feb 2021 14:43:13 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

Have you been exposed to someone with 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 (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2021-02-09T09:43:04', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '78b69b32-db79-47a6-8f1f-987e4900de73' | System | 09 Feb 2021 14:43:13 |
| User entered 'No (N)' | System | 09 Feb 2021 14:43:13 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2021-02-09T09:43:11', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '78b69b32-db79-47a6-8f1f-987e4900de73' User entered '09 Feb 2021 09:43:11' | System | 09 Feb 2021 14:43:13 |
| | System | 09 Feb 2021 14:43:13 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '07 Feb 2021 00:01' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '11 Feb 2021 23:59' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered 'Day 194' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[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 (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2021-02-16T21:48:36', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '41b60a5a-8adf-408e-9da9-706fc6b747b8' | System | 17 Feb 2021 03:50:17 |
| User entered 'No (N)' | System | 17 Feb 2021 03:50:17 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

Have you been exposed to someone with 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 (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2021-02-16T21:48:44', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '41b60a5a-8adf-408e-9da9-706fc6b747b8' | System | 17 Feb 2021 03:50:17 |
| User entered 'No (N)' | System | 17 Feb 2021 03:50:17 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2021-02-16T21:48:48', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '41b60a5a-8adf-408e-9da9-706fc6b747b8' User entered '16 Feb 2021 21:48:48' | System | 17 Feb 2021 03:50:17 |
| | System | 17 Feb 2021 03:50:17 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '14 Feb 2021 00:01' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '18 Feb 2021 23:59' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered 'Day 201' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[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 (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2021-02-21T15:34:08', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: 'fe6ec505-8abf-4b38-94f4-974c9bbac6db' User entered 'Yes (Y)' | System | 22 Feb 2021 14:59:24 |
| | System | 22 Feb 2021 14:59:24 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

Have you been exposed to someone with 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 (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2021-02-21T15:34:00', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: 'fe6ec505-8abf-4b38-94f4-974c9bbac6db' User entered 'No (N)' | System | 22 Feb 2021 14:59:24 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2021-02-21T15:33:58', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: 'fe6ec505-8abf-4b38-94f4-974c9bbac6db' User entered 'No (N)' | System | 22 Feb 2021 14:59:24 |
| | System | 22 Feb 2021 14:59:24 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2021-02-21T15:33:53', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: 'fe6ec505-8abf-4b38-94f4-974c9bbac6db' User entered 'Yes (Y)' | System | 22 Feb 2021 14:59:24 |
| | System | 22 Feb 2021 14:59:24 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

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

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2021-02-21T15:34:42', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: 'fe6ec505-8abf-4b38-94f4-974c9bbac6db' | System | 22 Feb 2021 14:59:24 |
| User entered 'I confirm I have read this message and will call the study clinic immediately (9)' | System | 22 Feb 2021 14:59:24 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2021-02-21T15:34:48', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: 'fe6ec505-8abf-4b38-94f4-974c9bbac6db' User entered '21 Feb 2021 15:34:48' | System | 22 Feb 2021 14:59:24 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '21 Feb 2021 00:01' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '25 Feb 2021 23:59' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered 'Day 208' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[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 (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2021-03-03T15:09:37-05:00', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '32b2610c-5cc2-41ac-ae86-2d23ca861f03' | System | 03 Mar 2021 20:09:49 |
| User entered 'No (N)' | System | 03 Mar 2021 20:09:49 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Have you been exposed to someone with 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 (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2021-03-03T15:09:41-05:00', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '32b2610c-5cc2-41ac-ae86-2d23ca861f03' | System | 03 Mar 2021 20:09:49 |
| User entered 'No (N)' | System | 03 Mar 2021 20:09:49 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2021-03-03T15:09:45-05:00', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '32b2610c-5cc2-41ac-ae86-2d23ca861f03' | System | 03 Mar 2021 20:09:49 |
| User entered '03 Mar 2021 15:09:45' | System | 03 Mar 2021 20:09:49 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '28 Feb 2021 00:01' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '04 Mar 2021 23:59' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered 'Day 215' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[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 (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2021-03-07T21:31:36-05:00', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '64e6533a-990b-4055-92d8-ce99a030c7b3' | System | 08 Mar 2021 02:36:45 |
| User entered 'No (N)' | System | 08 Mar 2021 02:36:45 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

Have you been exposed to someone with 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 (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2021-03-07T21:31:38-05:00', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '64e6533a-990b-4055-92d8-ce99a030c7b3' | System | 08 Mar 2021 02:36:45 |
| User entered 'No (N)' | System | 08 Mar 2021 02:36:45 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2021-03-07T21:31:42-05:00', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '64e6533a-990b-4055-92d8-ce99a030c7b3' | System | 08 Mar 2021 02:36:45 |
| User entered '07 Mar 2021 21:31:42' | System | 08 Mar 2021 02:36:45 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '07 Mar 2021 00:01' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '11 Mar 2021 23:59' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered 'Day 222' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[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 (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2021-03-15T15:34:43-04:00', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '629e49cc-0bc9-4008-9d3b-0d8be5704447' | System | 15 Mar 2021 19:34:55 |
| User entered 'No (N)' | System | 15 Mar 2021 19:34:55 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

Have you been exposed to someone with 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 (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2021-03-15T15:34:47-04:00', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '629e49cc-0bc9-4008-9d3b-0d8be5704447' | System | 15 Mar 2021 19:34:55 |
| User entered 'No (N)' | System | 15 Mar 2021 19:34:55 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2021-03-15T15:34:53-04:00', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '629e49cc-0bc9-4008-9d3b-0d8be5704447' | System | 15 Mar 2021 19:34:55 |
| User entered '15 Mar 2021 15:34:53' | System | 15 Mar 2021 19:34:55 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '14 Mar 2021 00:01' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '18 Mar 2021 23:59' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered 'Day 229' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[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 (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2021-03-23T17:18:49-04:00', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '8ac2be73-0311-43d9-acd9-21a90b3e7f2f' User entered 'No (N)' | System | 23 Mar 2021 21:19:04 |
| | System | 23 Mar 2021 21:19:04 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

Have you been exposed to someone with 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 (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2021-03-23T17:18:55-04:00', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '8ac2be73-0311-43d9-acd9-21a90b3e7f2f' | System | 23 Mar 2021 21:19:04 |
| User entered 'No (N)' | System | 23 Mar 2021 21:19:04 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2021-03-23T17:19:00-04:00', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '8ac2be73-0311-43d9-acd9-21a90b3e7f2f' User entered '23 Mar 2021 17:19:00' | System | 23 Mar 2021 21:19:04 |
| | System | 23 Mar 2021 21:19:04 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '21 Mar 2021 00:01' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '25 Mar 2021 23:59' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered 'Day 236' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[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 (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2021-03-29T14:14:08-04:00', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: 'fdbf16db-9007-45e7-b36f-050ebcdb3678' | System | 29 Mar 2021 18:14:25 |
| User entered 'No (N)' | System | 29 Mar 2021 18:14:25 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

Have you been exposed to someone with 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 (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2021-03-29T14:14:16-04:00', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: 'fdbf16db-9007-45e7-b36f-050ebcdb3678' | System | 29 Mar 2021 18:14:25 |
| User entered 'No (N)' | System | 29 Mar 2021 18:14:25 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2021-03-29T14:14:19-04:00', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: 'fdbf16db-9007-45e7-b36f-050ebcdb3678' User entered '29 Mar 2021 14:14:19' | System | 29 Mar 2021 18:14:25 |
| | System | 29 Mar 2021 18:14:25 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '28 Mar 2021 00:01' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '01 Apr 2021 23:59' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered 'Day 243' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[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 (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2021-04-05T09:34:31-04:00', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: 'e2c668a9-3c11-4aac-95d8-d79aa50f5e22' | System | 05 Apr 2021 13:35:08 |
| User entered 'Yes (Y)' | System | 05 Apr 2021 13:35:08 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Have you been exposed to someone with 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 (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2021-04-05T09:34:38-04:00', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: 'e2c668a9-3c11-4aac-95d8-d79aa50f5e22' | System | 05 Apr 2021 13:35:08 |
| User entered 'No (N)' | System | 05 Apr 2021 13:35:08 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2021-04-05T09:34:44-04:00', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: 'e2c668a9-3c11-4aac-95d8-d79aa50f5e22' | System | 05 Apr 2021 13:35:08 |
| User entered 'No (N)' | System | 05 Apr 2021 13:35:08 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2021-04-05T09:34:51-04:00', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: 'e2c668a9-3c11-4aac-95d8-d79aa50f5e22' | System | 05 Apr 2021 13:35:08 |
| User entered 'No (N)' | System | 05 Apr 2021 13:35:08 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2021-04-05T09:35:04-04:00', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: 'e2c668a9-3c11-4aac-95d8-d79aa50f5e22' | System | 05 Apr 2021 13:35:08 |
| User entered '05 Apr 2021 09:35:04' | System | 05 Apr 2021 13:35:08 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '04 Apr 2021 00:01' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '08 Apr 2021 23:59' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered 'Day 250' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '11 Apr 2021 00:01' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '15 Apr 2021 23:59' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered 'Day 257' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[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 (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2021-04-19T16:50:34-04:00', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '17a85867-7b9f-4578-af91-eca82b72f500' | System | 19 Apr 2021 20:50:55 |
| User entered 'No (N)' | System | 19 Apr 2021 20:50:55 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

Have you been exposed to someone with 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 (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2021-04-19T16:50:40-04:00', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '17a85867-7b9f-4578-af91-eca82b72f500' | System | 19 Apr 2021 20:50:55 |
| User entered 'No (N)' | System | 19 Apr 2021 20:50:55 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2021-04-19T16:50:44-04:00', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '17a85867-7b9f-4578-af91-eca82b72f500' | System | 19 Apr 2021 20:50:55 |
| User entered '19 Apr 2021 16:50:44' | System | 19 Apr 2021 20:50:55 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '18 Apr 2021 00:01' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '22 Apr 2021 23:59' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered 'Day 264' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[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 (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2021-04-27T20:59:49-04:00', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '00d6237c-2726-4e64-92b6-3a267b1f802d' | System | 29 Apr 2021 01:57:21 |
| User entered 'No (N)' | System | 29 Apr 2021 01:57:21 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

Have you been exposed to someone with 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 (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2021-04-27T20:59:52-04:00', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '00d6237c-2726-4e64-92b6-3a267b1f802d' User entered 'No (N)' | System | 29 Apr 2021 01:57:21 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2021-04-27T20:59:58-04:00', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '00d6237c-2726-4e64-92b6-3a267b1f802d' | System | 29 Apr 2021 01:57:21 |
| User entered '27 Apr 2021 20:59:58' | System | 29 Apr 2021 01:57:21 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '25 Apr 2021 00:01' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '29 Apr 2021 23:59' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered 'Day 271' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[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 (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2021-05-02T20:00:46-04:00', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: 'b6c77808-5724-411b-9cd3-e09cb25863df' | System | 03 May 2021 00:00:59 |
| User entered 'No (N)' | System | 03 May 2021 00:00:59 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

Have you been exposed to someone with 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 (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2021-05-02T20:00:50-04:00', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: 'b6c77808-5724-411b-9cd3-e09cb25863df' | System | 03 May 2021 00:00:59 |
| User entered 'No (N)' | System | 03 May 2021 00:00:59 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2021-05-02T20:00:53-04:00', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: 'b6c77808-5724-411b-9cd3-e09cb25863df' | System | 03 May 2021 00:00:59 |
| User entered '02 May 2021 20:00:53' | System | 03 May 2021 00:00:59 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '02 May 2021 00:01' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '06 May 2021 23:59' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered 'Day 278' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '09 May 2021 00:01' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '13 May 2021 23:59' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered 'Day 285' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '16 May 2021 00:01' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '20 May 2021 23:59' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered 'Day 292' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '23 May 2021 00:01' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '27 May 2021 23:59' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered 'Day 299' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '30 May 2021 00:01' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '03 Jun 2021 23:59' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered 'Day 306' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '06 Jun 2021 00:01' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '10 Jun 2021 23:59' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered 'Day 313' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '13 Jun 2021 00:01' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '17 Jun 2021 23:59' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered 'Day 320' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '20 Jun 2021 00:01' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '24 Jun 2021 23:59' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered 'Day 327' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '27 Jun 2021 00:01' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '01 Jul 2021 23:59' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered 'Day 334' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '04 Jul 2021 00:01' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '08 Jul 2021 23:59' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered 'Day 341' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '11 Jul 2021 00:01' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '15 Jul 2021 23:59' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered 'Day 348' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '18 Jul 2021 00:01' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '22 Jul 2021 23:59' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered 'Day 355' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '25 Jul 2021 00:01' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '29 Jul 2021 23:59' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered 'Day 362' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '01 Aug 2021 00:01' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '05 Aug 2021 23:59' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered 'Day 369' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '08 Aug 2021 00:01' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '12 Aug 2021 23:59' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered 'Day 376' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '15 Aug 2021 00:01' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '19 Aug 2021 23:59' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered 'Day 383' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '22 Aug 2021 00:01' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '26 Aug 2021 23:59' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered 'Day 390' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '29 Aug 2021 00:01' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '02 Sep 2021 23:59' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered 'Day 397' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '05 Sep 2021 00:01' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '09 Sep 2021 23:59' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered 'Day 404' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '12 Sep 2021 00:01' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '16 Sep 2021 23:59' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered 'Day 411' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '19 Sep 2021 00:01' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '23 Sep 2021 23:59' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered 'Day 418' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '26 Sep 2021 00:01' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '30 Sep 2021 23:59' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered 'Day 425' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '03 Oct 2021 00:01' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '07 Oct 2021 23:59' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered 'Day 432' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '10 Oct 2021 00:01' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '14 Oct 2021 23:59' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered 'Day 439' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '17 Oct 2021 00:01' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '21 Oct 2021 23:59' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered 'Day 446' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '24 Oct 2021 00:01' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '28 Oct 2021 23:59' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered 'Day 453' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '31 Oct 2021 00:01' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '04 Nov 2021 23:59' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered 'Day 460' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '07 Nov 2021 00:01' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '11 Nov 2021 23:59' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered 'Day 467' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '14 Nov 2021 00:01' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '18 Nov 2021 23:59' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered 'Day 474' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '21 Nov 2021 00:01' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '25 Nov 2021 23:59' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered 'Day 481' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '28 Nov 2021 00:01' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '02 Dec 2021 23:59' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered 'Day 488' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '05 Dec 2021 00:01' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '09 Dec 2021 23:59' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered 'Day 495' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '12 Dec 2021 00:01' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '16 Dec 2021 23:59' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered 'Day 502' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '19 Dec 2021 00:01' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '23 Dec 2021 23:59' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered 'Day 509' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '26 Dec 2021 00:01' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '30 Dec 2021 23:59' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered 'Day 516' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '02 Jan 2022 00:01' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '06 Jan 2022 23:59' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered 'Day 523' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '09 Jan 2022 00:01' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '13 Jan 2022 23:59' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered 'Day 530' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '16 Jan 2022 00:01' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '20 Jan 2022 23:59' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered 'Day 537' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '23 Jan 2022 00:01' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '27 Jan 2022 23:59' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered 'Day 544' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '30 Jan 2022 00:01' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '03 Feb 2022 23:59' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered 'Day 551' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '06 Feb 2022 00:01' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '10 Feb 2022 23:59' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered 'Day 558' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '13 Feb 2022 00:01' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '17 Feb 2022 23:59' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered 'Day 565' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '20 Feb 2022 00:01' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '24 Feb 2022 23:59' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered 'Day 572' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '27 Feb 2022 00:01' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '03 Mar 2022 23:59' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered 'Day 579' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '06 Mar 2022 00:01' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '10 Mar 2022 23:59' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered 'Day 586' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '13 Mar 2022 00:01' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '17 Mar 2022 23:59' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered 'Day 593' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '20 Mar 2022 00:01' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '24 Mar 2022 23:59' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered 'Day 600' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '27 Mar 2022 00:01' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '31 Mar 2022 23:59' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered 'Day 607' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '03 Apr 2022 00:01' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '07 Apr 2022 23:59' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered 'Day 614' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '10 Apr 2022 00:01' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '14 Apr 2022 23:59' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered 'Day 621' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '17 Apr 2022 00:01' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '21 Apr 2022 23:59' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered 'Day 628' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '24 Apr 2022 00:01' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '28 Apr 2022 23:59' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered 'Day 635' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '01 May 2022 00:01' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '05 May 2022 23:59' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered 'Day 642' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '08 May 2022 00:01' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '12 May 2022 23:59' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered 'Day 649' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '15 May 2022 00:01' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '19 May 2022 23:59' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered 'Day 656' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '22 May 2022 00:01' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '26 May 2022 23:59' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered 'Day 663' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '29 May 2022 00:01' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '02 Jun 2022 23:59' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered 'Day 670' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '05 Jun 2022 00:01' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '09 Jun 2022 23:59' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered 'Day 677' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '12 Jun 2022 00:01' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '16 Jun 2022 23:59' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered 'Day 684' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '19 Jun 2022 00:01' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '23 Jun 2022 23:59' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered 'Day 691' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '26 Jun 2022 00:01' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '30 Jun 2022 23:59' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered 'Day 698' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '03 Jul 2022 00:01' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '07 Jul 2022 23:59' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered 'Day 705' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '10 Jul 2022 00:01' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '14 Jul 2022 23:59' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered 'Day 712' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '17 Jul 2022 00:01' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '21 Jul 2022 23:59' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered 'Day 719' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '24 Jul 2022 00:01' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '28 Jul 2022 23:59' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered 'Day 726' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '31 Jul 2022 00:01' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '04 Aug 2022 23:59' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered 'Day 733' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '07 Aug 2022 00:01' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '11 Aug 2022 23:59' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered 'Day 740' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '14 Aug 2022 00:01' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '18 Aug 2022 23:59' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered 'Day 747' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '21 Aug 2022 00:01' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '25 Aug 2022 23:59' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered 'Day 754' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '28 Aug 2022 00:01' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '01 Sep 2022 23:59' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered 'Day 761' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '04 Sep 2022 00:01' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '08 Sep 2022 23:59' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered 'Day 768' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '11 Sep 2022 00:01' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '15 Sep 2022 23:59' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered 'Day 775' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '18 Sep 2022 00:01' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '22 Sep 2022 23:59' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered 'Day 782' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '25 Sep 2022 00:01' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '29 Sep 2022 23:59' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered 'Day 789' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '02 Oct 2022 00:01' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '06 Oct 2022 23:59' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered 'Day 796' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '09 Oct 2022 00:01' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:57:13

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:14:43 |
| Amendment Manager: User entered '13 Oct 2022 23:59' | System | 19 Nov 2020 16:14:43 |

US3302105

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 16:57:13

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 04:55:32 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2021-03-03T15:09:53-05:00', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '7e5de84c-af6d-46a0-b29c-8424425af1da' | System | 03 Mar 2021 20:10:05 |
| User entered 'No (N)' | System | 03 Mar 2021 20:10:05 |

US3302105

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 16:57:13

[Date & Time of Submission](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 04:55:32 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C1D05D73-E01C-4DD4-9B85-55CAA549EE1E)', Time: '2021-03-03T15:10:00-05:00', User OID: 'PatientReportedOutcome (US3302105)', ODM File OID: '7e5de84c-af6d-46a0-b29c-8424425af1da' | System | 03 Mar 2021 20:10:05 |
| User entered '03 Mar 2021 15:10:00' | System | 03 Mar 2021 20:10:05 |

US3302105

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:57:13

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:40 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:03:00 |
| User entered 'Yes (Y)' | (b) (4) Brittany Belcher (b) (4) | 30 Oct 2020 13:04:18 |

US3302105

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:57:13

Date of Contact or Contact Attempt (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:40 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:03:00 |
| User entered '30 Oct 2020' | (b) (4) Brittany Belcher (b) (4) | 30 Oct 2020 13:04:18 |

US3302105

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:57:13

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:40 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:03:00 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4) Brittany Belcher (b) (4) | 30 Oct 2020 13:04:18 |

US3302105

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:57:13

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:40 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:03:00 |
| User entered empty. | (b) (4) Brittany Belcher (b) (4) | 30 Oct 2020 13:04:18 |

US3302105

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:57:13

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:40 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:03:00 |
| User entered 'Yes (Y)' | (b) (4) Brittany Belcher (b) (4) | 30 Oct 2020 13:04:21 |

US3302105

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:57:13

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Mar 2021 02:20:40 |
| User entered 'I' | System | 30 Oct 2020 13:04:21 |

US3302105

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:57:13

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 07:00:43 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:02:55 |
| User entered 'Yes (Y)' | (b) (4) Brittany Belcher (b) (4) | 04 Dec 2020 14:03:59 |

US3302105

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:57:13

Date of Contact or Contact Attempt (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 07:00:43 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:02:55 |
| User entered '4 Dec 2020' | (b) (4) Brittany Belcher (b) (4) | 04 Dec 2020 14:03:59 |

US3302105

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:57:13

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 07:00:43 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:02:55 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4) Brittany Belcher (b) (4) | 04 Dec 2020 14:03:59 |

US3302105

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:57:13

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 07:00:43 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:02:55 |
| User entered empty. | (b) (4) Brittany Belcher (b) (4) | 04 Dec 2020 14:03:59 |

US3302105

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:57:13

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 07:00:43 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:02:55 |
| User entered 'Yes (Y)' | (b) (4) Brittany Belcher (b) (4) | 04 Dec 2020 14:04:03 |

US3302105

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:57:13

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 07:00:43 |
| User entered 'I' | System | 04 Dec 2020 14:04:03 |

US3302105

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:57:13

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 07:00:43 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:02:55 |
| User entered 'Yes (Y)' | Kendal Nelson (b) (4) | 04 Jan 2021 19:44:02 |

US3302105

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:57:13

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 07:00:43 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:02:55 |
| User entered '4 Jan 2021' | Kendal Nelson (b) (4) | 04 Jan 2021 19:44:02 |

US3302105

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:57:13

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 07:00:43 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:02:55 |
| User entered 'Contact Made (CONTACT MADE)' | Kendal Nelson (b) (4) | 04 Jan 2021 19:44:02 |

US3302105

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:57:13

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 07:00:43 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:02:55 |
| User entered empty. | Kendal Nelson (b) (4) | 04 Jan 2021 19:44:02 |

US3302105

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:57:13

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 07:00:43 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:02:55 |
| User entered 'Yes (Y)' | Kendal Nelson (b) (4) | 04 Jan 2021 19:44:08 |

US3302105

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:57:13

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 07:00:43 |
| User entered 'I' | System | 04 Jan 2021 19:44:08 |

US3302105

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:57:13

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 07:00:43 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:02:55 |
| User entered 'Yes (Y)' | (b) (4) Wendy Taylor (b) (4) | 02 Feb 2021 13:47:35 |

US3302105

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:57:13

Date of Contact or Contact Attempt (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 07:00:43 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:02:55 |
| User entered '02 Feb 2021' reason for change: Data Entry Error | (b) (4) Wendy Taylor (b) (4) | 02 Feb 2021 14:12:46 |
| User entered '2 Feb 2021' | (b) (4) Wendy Taylor (b) (4) | 02 Feb 2021 13:47:35 |

US3302105

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:57:13

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 07:00:43 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:02:55 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4) Wendy Taylor (b) (4) | 02 Feb 2021 13:47:35 |

US3302105

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:57:13

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 07:00:43 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:02:55 |
| User entered empty. | (b) (4) Wendy Taylor (b) (4) | 02 Feb 2021 13:47:35 |

US3302105

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:57:13

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 07:00:43 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:02:55 |
| User entered 'Yes (Y)' | Wendy Taylor (b) (4) | 02 Feb 2021 13:47:40 |

US3302105

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:57:13

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 07:00:43 |
| User entered 'I' | System | 02 Feb 2021 13:47:40 |

US3302105

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:57:13

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 07:00:43 |
| User signature succeeded. | Gregory Feldman (b) (4) | 03 Mar 2021 18:51:48 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 02 Mar 2021 20:40:35 |

US3302105

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:57:13

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 07:00:43 |
| User signature succeeded. | Gregory Feldman (b) (4) | 03 Mar 2021 18:51:48 |
| User entered '02 Mar 2021' | (b) (4) (b) (4), (b) (6) | 02 Mar 2021 20:40:35 |

US3302105

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:57:13

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

| Audit | User | Time (GMT) |
|--------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 07:00:43 |
| User signature succeeded. | Gregory Feldman (b) (4) | 03 Mar 2021 18:51:48 |
| User entered 'Clinic (Clinic)' | (b) (4) (b) (4), (b) (6) | 02 Mar 2021 20:40:35 |

US3302105

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:57:13

[Folder OID](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 07:00:43 |
| User entered 'VISIT4' | System | 02 Mar 2021 20:40:35 |

US3302105

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:57:13

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 07:00:43 |
| User signature succeeded. | Gregory Feldman (b) (4) | 02 Apr 2021 15:49:48 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 31 Mar 2021 15:03:50 |

US3302105

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:57:13

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 07:00:43 |
| User signature succeeded. | Gregory Feldman (b) (4) | 02 Apr 2021 15:49:48 |
| User entered '02 Mar 2021' | (b) (4) (b) (4), (b) (6) | 31 Mar 2021 15:03:50 |

US3302105

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:57:13

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

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 07:00:43 |
| User signature succeeded. | Gregory Feldman (b) (4) | 02 Apr 2021 15:49:48 |
| User entered '08:06' | (b) (4), (b) (6) | 31 Mar 2021 15:03:50 |

US3302105

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:57:13

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 07:00:43 |
| User entered '02 Mar 2021 08:06' | System | 31 Mar 2021 15:03:50 |

US3302105

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:57:13

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 07:00:43 |
| User signature succeeded. | Gregory Feldman (b) (4) | 02 Apr 2021 15:49:48 |
| User entered '97.8' F | (b) (4), (b) (6) | 31 Mar 2021 15:03:50 |

US3302105

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:57:13

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 07:00:43 |
| User signature succeeded. | Gregory Feldman (b) (4) | 02 Apr 2021 15:49:48 |
| User entered 'Oral (Oral)' | (b) (4) (b) (4), (b) (6) | 31 Mar 2021 15:03:50 |

US3302105

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:57:13

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 07:00:43 |
| User signature succeeded. | Gregory Feldman (b) (4) | 02 Apr 2021 15:49:48 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 31 Mar 2021 15:03:50 |

US3302105

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:57:13

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 07:00:43 |
| User signature succeeded. | Gregory Feldman (b) (4) | 02 Apr 2021 15:49:48 |
| User entered '67' | (b) (4) (b) (4), (b) (6) | 31 Mar 2021 15:03:50 |

US3302105

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:57:13

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 07:00:43 |
| User entered 'bpm' | System | 31 Mar 2021 15:03:50 |

US3302105

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:57:13

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 07:00:43 |
| User signature succeeded. | Gregory Feldman (b) (4) | 02 Apr 2021 15:49:48 |
| User entered '18' | (b) (4) (b) (4), (b) (6) | 31 Mar 2021 15:03:50 |

US3302105

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:57:13

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 07:00:43 |
| User entered 'breaths/min' | System | 31 Mar 2021 15:03:50 |

US3302105

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:57:13

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 07:00:43 |
| User signature succeeded. | Gregory Feldman (b) (4) | 02 Apr 2021 15:49:48 |
| User entered '139' | (b) (4) (b) (4), (b) (6) | 31 Mar 2021 15:03:50 |

US3302105

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:57:13

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 07:00:43 |
| User entered 'mmHg' | System | 31 Mar 2021 15:03:50 |

US3302105

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:57:13

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 07:00:43 |
| User signature succeeded. | Gregory Feldman (b) (4) | 02 Apr 2021 15:49:48 |
| User entered '78' | (b) (4) (b) (4), (b) (6) | 31 Mar 2021 15:03:50 |

US3302105

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:57:13

[Diastolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 07:00:43 |
| User entered 'mmHg' | System | 31 Mar 2021 15:03:50 |

US3302105

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:57:13

[Height \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 07:00:43 |

US3302105

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:57:13

Weight (derived)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 07:00:43 |

US3302105

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:57:13

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 07:00:43 |
| User signature succeeded. | Gregory Feldman (b) (4) | 03 Mar 2021 18:51:48 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 02 Mar 2021 20:40:43 |

US3302105

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:57:13

Date of examination (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 07:00:43 |
| User signature succeeded. | Gregory Feldman (b) (4) | 03 Mar 2021 18:51:48 |
| User entered '02 Mar 2021' | (b) (4) (b) (4), (b) (6) | 02 Mar 2021 20:40:43 |

US3302105

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:57:13

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 07:00:43 |
| User signature succeeded. | Gregory Feldman (b) (4) | 03 Mar 2021 18:51:48 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 02 Mar 2021 20:40:52 |

US3302105

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:57:13

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 07:00:43 |
| User signature succeeded. | Gregory Feldman (b) (4) | 03 Mar 2021 18:51:48 |
| User entered '02 Mar 2021' | (b) (4) (b) (4), (b) (6) | 02 Mar 2021 20:40:52 |

US3302105

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:57:13

[Collection time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 07:00:43 |
| User signature succeeded. | Gregory Feldman (b) (4) | 03 Mar 2021 18:51:48 |
| User entered '08:13' | (b) (4) (b) (4), (b) (6) | 02 Mar 2021 20:40:52 |

US3302105

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:57:13

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 07:00:43 |
| User entered '02 Mar 2021 08:13' | System | 02 Mar 2021 20:40:52 |

US3302105

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:57:13

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 07:00:43 |
| User signature succeeded. | Gregory Feldman (b) (4) | 03 Mar 2021 18:51:48 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 02 Mar 2021 20:40:55 |

US3302105

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:57:13

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 07:00:43 |
| User entered 'I' | System | 02 Mar 2021 20:40:55 |

US3302105

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:57:13

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 20:49:53 |
| User signature succeeded. | Gregory Feldman (b) (4) | 02 Apr 2021 15:49:48 |
| User entered 'Yes (Y)' | Wendy Taylor (b) (4) | 30 Mar 2021 16:20:18 |

US3302105

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:57:13

Date of Contact or Contact Attempt (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 20:49:53 |
| User signature succeeded. | Gregory Feldman (b) (4) | 02 Apr 2021 15:49:48 |
| User entered '30 Mar 2021' | (b) (4) Wendy Taylor (b) (4) | 30 Mar 2021 16:20:18 |

US3302105

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:57:13

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 20:49:53 |
| User signature succeeded. | Gregory Feldman (b) (4) | 02 Apr 2021 15:49:48 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4) Wendy Taylor (b) (4) | 30 Mar 2021 16:20:18 |

US3302105

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:57:13

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 20:49:53 |
| User signature succeeded. | Gregory Feldman (b) (4) | 02 Apr 2021 15:49:48 |
| User entered empty. | (b) (4) Wendy Taylor (b) (4) | 30 Mar 2021 16:20:18 |

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Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:57:13

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 20:49:53 |
| User signature succeeded. | Gregory Feldman (b) (4) | 02 Apr 2021 15:49:48 |
| User entered 'Yes (Y)' | Wendy Taylor (b) (4) | 30 Mar 2021 16:20:27 |

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Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:57:13

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 20:49:53 |
| User entered 'I' | System | 30 Mar 2021 16:20:27 |

US3302105

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:57:13

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 30 Apr 2021 17:27:11 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Wendy Taylor (b) (4) | 29 Apr 2021 15:22:09 |
| | | |
| | | |

US3302105

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:57:13

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 30 Apr 2021 17:27:11 |
| | (b) (4) | |
| User entered '29 Apr 2021' | Wendy Taylor (b) (4) | 29 Apr 2021 15:22:09 |
| | | |
| | | |

US3302105

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:57:13

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 30 Apr 2021 17:27:11 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4) Wendy Taylor (b) (4) | 29 Apr 2021 15:22:09 |
| | | |
| | | |

US3302105

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:57:13

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 30 Apr 2021 17:27:11 |
| User entered empty. | (b) (4) | |
| | Wendy Taylor (b) (4) | 29 Apr 2021 15:22:09 |
| | | |
| | | |

US3302105

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:57:13

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 30 Apr 2021 17:27:11 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Wendy Taylor (b) (4) | 29 Apr 2021 15:22:14 |
| | | |
| | | |

US3302105

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:57:13

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 29 Apr 2021 15:22:14 |

US3302105

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

Form: Visit Date

Generated On: 09 Jun 2021 16:57:13

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:45:52 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:02:55 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 07 Jan 2021 22:54:27 |

US3302105

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

Form: Visit Date

Generated On: 09 Jun 2021 16:57:13

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:45:52 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:02:55 |
| User entered '07 Jan 2021' | (b) (4) (b) (4), (b) (6) | 07 Jan 2021 22:54:27 |

US3302105

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

Form: Visit Date

Generated On: 09 Jun 2021 16:57:13

[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 19:45:52 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:02:55 |
| User entered 'Clinic (Clinic)' | (b) (4) (b) (4), (b) (6) | 07 Jan 2021 22:54:27 |

US3302105

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

Form: Visit Date

Generated On: 09 Jun 2021 16:57:13

[Folder OID](#)

| Audit | User | Time (GMT) |
|------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:45:52 |
| User entered 'UNBLND_DECIDE' | System | 07 Jan 2021 22:54:27 |

US3302105

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

Form: Unblinding

Generated On: 09 Jun 2021 16:57:13

Date of updated informed consent (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:45:52 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:02:55 |
| User entered '07 Jan 2021' | (b) (4), (b) (6) | 07 Jan 2021 22:54:39 |

US3302105

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

Form: Unblinding

Generated On: 09 Jun 2021 16:57:13

[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 19:45:52 |
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 09 Apr 2021 14:15:03 |
| Amendment Manager inserted this DataPoint. | System | 06 Mar 2021 11:56:15 |

US3302105

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

Form: Unblinding

Generated On: 09 Jun 2021 16:57:13

[Was the participant unblinded?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:45:52 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:02:55 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 07 Jan 2021 22:54:39 |

US3302105

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

Form: Unblinding

Generated On: 09 Jun 2021 16:57:13

[Under what version of the Protocol was the Participant unblinded?](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:45:52 |
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| User closed query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field. ' (Site from DM). | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 07:42:23 |
| Query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field. ' answered with 'updated' (Site from DM). | (b) (4), (b) (6) | 09 Apr 2021 14:15:29 |
| User entered 'Amendment 6 or later (Amendment 6 or later)' | (b) (4), (b) (6) | 09 Apr 2021 14:15:03 |
| User opened query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field. ' (Site from DM). | (b) (4), (b) (6) | 08 Apr 2021 15:37:03 |
| Amendment Manager inserted this DataPoint. | System | 06 Mar 2021 11:56:15 |

US3302105

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

Form: Unblinding

Generated On: 09 Jun 2021 16:57:13

Date of unblinding (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:45:52 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:02:55 |
| User entered '07 Jan 2021' | (b) (4), (b) (6) | 07 Jan 2021 22:54:39 |

US3302105

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

Form: Unblinding

Generated On: 09 Jun 2021 16:57:13

[Participant randomization assignment](#)

| Audit | User | Time (GMT) |
|--------------------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:45:52 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:02:55 |
| User entered 'mRNA-1273 (mRNA-1273)' | (b) (4), (b) (6) | 07 Jan 2021 22:54:39 |

US3302105

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

Form: Unblinding

Generated On: 09 Jun 2021 16:57:13

[Actual Dose 1](#)

| Audit | User | Time (GMT) |
|---|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:45:52 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:02:55 |
| Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)' | (b) (4) System | 20 Jan 2021 06:43:12 |
| User entered 'mRNA-1273 (mRNA-1273)' | (b) (4), (b) (6) | 07 Jan 2021 22:54:39 |

US3302105

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

Form: Unblinding

Generated On: 09 Jun 2021 16:57:13

[Actual Dose 2](#)

| Audit | User | Time (GMT) |
|---|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:45:52 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:02:55 |
| Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)' | (b) (4) System | 20 Jan 2021 06:43:12 |
| User entered 'mRNA-1273 (mRNA-1273)' | (b) (4), (b) (6) | 07 Jan 2021 22:54:39 |

US3302105

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

Form: Unblinding

Generated On: 09 Jun 2021 16:57:13

[Will participant receive mRNA-1273?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:45:52 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:02:55 |
| User entered 'No (N)' | (b) (4), (b) (6) | 07 Jan 2021 22:54:39 |

US3302105

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

Form: Unblinding

Generated On: 09 Jun 2021 16:57:13

[Placebo Only Flag](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:45:52 |
| User entered empty. | System | 07 Jan 2021 22:54:39 |

US3302105

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

Form: Unblinding

Generated On: 09 Jun 2021 16:57:13

[Continuing with mRNA-1273](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:45:52 |
| User entered empty. | System | 07 Jan 2021 22:54:39 |

US3302105

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:57:13

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:45:52 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:02:55 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 07 Jan 2021 22:54:48 |

US3302105

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:57:13

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:45:52 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:02:55 |
| User entered '07 Jan 2021' | (b) (4), (b) (6) | 07 Jan 2021 22:54:48 |

US3302105

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:57:13

[Collection time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:45:52 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:02:55 |
| User entered '15:22' | (b) (4), (b) (6) | 07 Jan 2021 22:54:48 |

US3302105

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:57:13

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:45:52 |
| User entered '07 Jan 2021 15:22' | System | 07 Jan 2021 22:54:48 |

US3302105

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:57:13

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:45:52 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:02:55 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 07 Jan 2021 22:54:56 |

US3302105

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:57:13

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:45:52 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:02:55 |
| User entered '07 Jan 2021' | (b) (4), (b) (6) | 07 Jan 2021 22:54:56 |

US3302105

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:57:13

[Collection time \(00:00 - 23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:45:52 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:02:55 |
| User entered '15:20' | (b) (4), (b) (6) | 07 Jan 2021 22:54:56 |

US3302105

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:57:13

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:45:52 |
| User entered '07 Jan 2021 15:20' | System | 07 Jan 2021 22:54:56 |

US3302105

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 16:57:13

[Did the participant experience any adverse events?](#)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 05:15:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 31 Mar 2021 20:43:26 |
| Query 'Per DM CLR: Per Day 201 on Safety Follow-up Diary, Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' canceled (Site from DM). | (b) (4), (b) (6) | 22 Mar 2021 07:27:59 |
| User opened query 'Per DM CLR: Per Day 201 on Safety Follow-up Diary, Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' (Site from DM). | (b) (4), (b) (6) | 21 Mar 2021 03:17:30 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:02:55 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 05 Feb 2021 14:54:20 |

US3302105

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:57:13

[AEID](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 09:48:15 |
| | | |

US3302105

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:57:13

[Adverse event](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 09:48:15 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:02:55 |
| User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Dental and oral soft tissue infections, PT: Tooth abscess, LLT: Tooth abscess - version MedDRA\\23.0. | (b) (4) Coder Import (b) (4) | 05 Feb 2021 14:56:42 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 05 Feb 2021 14:56:42 |
| Data point term sent to Coder | System | 05 Feb 2021 14:55:59 |
| User entered 'tooth abscess' | (b) (4), (b) (6) | 05 Feb 2021 14:55:11 |
| | | |
| | | |

US3302105

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:57:13

[Was this a medically-attended AE?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 09:48:15 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:02:55 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 05 Feb 2021 14:55:11 |

US3302105

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:57:13

[Was this a Solicited Adverse Reaction?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 09:48:15 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:02:55 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 05 Feb 2021 14:55:11 |

US3302105

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:57:13

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 09:48:15 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:02:55 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 05 Feb 2021 14:55:11 |

US3302105

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:57:13

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 09:48:15 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:02:55 |
| User entered '18 Jan 2021' | (b) (4) (b) (4), (b) (6) | 05 Feb 2021 14:55:11 |

US3302105

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:57:13

[Start time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 09:48:15 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:02:55 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 05 Feb 2021 14:55:11 |

US3302105

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:57:13

[AE start date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 09:48:15 |
| User entered empty. | System | 05 Feb 2021 14:55:11 |

US3302105

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:57:13

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 09:48:15 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:02:55 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 05 Feb 2021 14:55:11 |

US3302105

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:57:13

If not Ongoing, end date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 09:48:15 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:02:55 |
| User entered '30 Jan 2021' | (b) (4) (b) (4), (b) (6) | 05 Feb 2021 14:55:11 |

US3302105

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:57:13

[End time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 09:48:15 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:02:55 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 05 Feb 2021 14:55:11 |

US3302105

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:57:13

[AE End Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 09:48:15 |
| User entered empty. | System | 05 Feb 2021 14:55:11 |

US3302105

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:57:13

[Severity](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 09:48:15 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:02:55 |
| User entered 'Grade 1/Mild (Grade 1/Mild)' | (b) (4) (b) (4), (b) (6) | 05 Feb 2021 14:55:11 |

US3302105

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:57:13

[Is the adverse event serious?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 09:48:15 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:02:55 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 05 Feb 2021 14:55:11 |

US3302105

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:57:13

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 09:48:15 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:02:55 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 05 Feb 2021 14:55:11 |

US3302105

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:57:13

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 09:48:15 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:02:55 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 05 Feb 2021 14:55:11 |

US3302105

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:57:13

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 09:48:15 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:02:55 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 05 Feb 2021 14:55:11 |

US3302105

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:57:13

Hospital Admission Date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 09:48:15 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:02:55 |
| User entered empty. | (b) (4), (b) (6) | 05 Feb 2021 14:55:11 |

US3302105

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:57:13

Hospital Discharge Date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 09:48:15 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:02:55 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 05 Feb 2021 14:55:11 |

US3302105

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:57:13

[Admitted to ICU?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 09:48:15 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:02:55 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 05 Feb 2021 14:55:11 |

US3302105

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:57:13

[Number of Days in ICU](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 09:48:15 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:02:55 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 05 Feb 2021 14:55:11 |

US3302105

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:57:13

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 09:48:15 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:02:55 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 05 Feb 2021 14:55:11 |

US3302105

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:57:13

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 09:48:15 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:02:55 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 05 Feb 2021 14:55:11 |

US3302105

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:57:13

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 09:48:15 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:02:55 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 05 Feb 2021 14:55:11 |

US3302105

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:57:13

[Relationship to investigational product](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 09:48:15 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:02:55 |
| User entered 'Not Related (NOT RELATED)' | (b) (4) (b) (4), (b) (6) | 05 Feb 2021 14:55:11 |

US3302105

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:57:13

[Relationship to Study Procedure](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 09:48:15 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:02:55 |
| User entered 'Not Related (NOT RELATED)' | (b) (4) (b) (4), (b) (6) | 05 Feb 2021 14:55:11 |

US3302105

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:57:13

[Action taken with investigational product](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 09:48:15 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:02:55 |
| User entered 'None (NONE)' | (b) (4) (b) (4), (b) (6) | 05 Feb 2021 14:55:11 |

US3302105

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:57:13

None

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 09:48:15 |
| User signature succeeded. | Gregory Feldman (b) (4) | 29 Apr 2021 12:33:05 |
| Signature has been broken. | (b) (4) Brittany Belcher (b) (4) | 26 Apr 2021 13:07:33 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:02:55 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 05 Feb 2021 14:55:11 |

US3302105

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:57:13

[Concomitant Medication](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 09:48:15 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:02:55 |
| User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM). | (b) (4) (b) (4), (b) (6) | 17 Feb 2021 07:39:12 |
| Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' answered with 'updated.' (Site from DM). | Brittany Belcher (b) (4) | 16 Feb 2021 16:40:20 |
| User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM). | (b) (4), (b) (6) | 16 Feb 2021 04:00:47 |
| User entered 'I' | (b) (4), (b) (6) | 05 Feb 2021 14:55:11 |

US3302105

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:57:13

[Concomitant Procedure](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 09:48:15 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:02:55 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 05 Feb 2021 14:55:11 |

US3302105

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:57:13

[Outcome](#)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 09:48:15 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:02:55 |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' | (b) (4), (b) (6) | 05 Feb 2021 14:55:11 |

US3302105

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:57:13

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 09:48:15 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:02:55 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 05 Feb 2021 14:55:11 |

US3302105

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:57:13

[Narrative](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 09:48:15 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:02:55 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 05 Feb 2021 14:55:11 |

US3302105

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:57:13

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 09:48:15 |
| User entered '0' | System | 05 Feb 2021 14:55:11 |

US3302105

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:57:13

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 09:48:15 |
| User entered 'I' | System | 05 Feb 2021 14:55:11 |

US3302105

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:57:13

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 09:48:15 |
| | | |

US3302105

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:57:13

[AEID](#)

| Audit | User | Time (GMT) |
|---|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 31 Mar 2021 20:50:18 |
| User signature succeeded. | Gregory Feldman (b) (4) | 05 Mar 2021 21:40:02 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:18:10 |
| User entered 'USA-US087-2021-mRNA-1273-P301000020' | System | 22 Feb 2021 19:17:20 |
| User entered 'New' | (b) (4), (b) (6) | 22 Feb 2021 19:17:20 |

US3302105

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:57:13

[Adverse event](#)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 31 Mar 2021 20:50:21 |
| User signature succeeded. | Gregory Feldman (b) (4) | 05 Mar 2021 21:40:02 |
| User coded data point as SOC: Cardiac disorders, HLT: Coronary artery disorders, HLT: Ischaemic coronary artery disorders, PT: Myocardial infarction, LLT: Myocardial infarction - version MedDRA\\23.0. | Coder Import (b) (4) | 22 Feb 2021 13:45:58 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 22 Feb 2021 13:45:58 |
| Data point term sent to Coder | System | 22 Feb 2021 13:45:04 |
| User entered 'myocardial infarction' | marsha gossett (b) (4) | 22 Feb 2021 13:44:19 |

US3302105

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:57:13

[Was this a medically-attended AE?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 31 Mar 2021 20:50:27 |
| User signature succeeded. | Gregory Feldman (b) (4) | 05 Mar 2021 21:40:02 |
| User entered 'Yes (Y)' | marsha gossett (b) (4) | 22 Feb 2021 13:44:19 |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:57:13

[Was this a Solicited Adverse Reaction?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 31 Mar 2021 20:50:30 |
| User signature succeeded. | Gregory Feldman (b) (4) | 05 Mar 2021 21:40:02 |
| User entered 'No (N)' | marsha gossett (b) (4) | 22 Feb 2021 13:44:19 |

US3302105

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:57:13

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 31 Mar 2021 20:50:31 |
| User signature succeeded. | Gregory Feldman (b) (4) | 05 Mar 2021 21:40:02 |
| User entered 'No (N)' | marsha gossett (b) (4) | 22 Feb 2021 13:44:19 |

US3302105

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:57:13

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

| Audit | User | Time (GMT) |
|----------------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 31 Mar 2021 20:50:34 |
| User signature succeeded. | Gregory Feldman (b) (4) | 05 Mar 2021 21:40:02 |
| User entered '19 Feb 2021' | marsha gossett (b) (4) | 22 Feb 2021 13:44:19 |

US3302105

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:57:13

[Start time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 31 Mar 2021 20:50:36 |
| User signature succeeded. | Gregory Feldman (b) (4) | 05 Mar 2021 21:40:02 |
| User entered empty. | marsha gossett (b) (4) | 22 Feb 2021 13:44:19 |

US3302105

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:57:13

[AE start date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 22 Feb 2021 13:44:19 |

US3302105

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:57:13

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 31 Mar 2021 20:50:39 |
| Signature has been broken. | Brittany Belcher (b) (4) | 15 Mar 2021 17:24:27 |
| | | |
| User entered 'No (N)' reason for change: Data Entry Error | Brittany Belcher (b) (4) | 15 Mar 2021 17:24:27 |
| | | |
| User signature succeeded. | Gregory Feldman (b) (4) | 05 Mar 2021 21:40:02 |
| | (b) (4) | |
| User entered 'Yes (Y)' | marsha gossett (b) (4) | 22 Feb 2021 13:44:19 |
| | (b) (4) | |

US3302105

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:57:13

If not Ongoing, end date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 31 Mar 2021 20:50:41 |
| User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. ' (Site from Safety). | (b) (4), (b) (6) | 16 Mar 2021 15:28:00 |
| User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System). | System | 15 Mar 2021 17:24:55 |
| Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System). | System | 15 Mar 2021 17:24:55 |
| Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. ' answered with 'updated.' (Site from Safety). | Brittany Belcher (b) (4) | 15 Mar 2021 17:24:35 |
| User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System). | System | 15 Mar 2021 17:24:27 |
| Signature has been broken. | Brittany Belcher (b) (4) | 15 Mar 2021 17:24:27 |
| User entered '19 Feb 2021' reason for change: Data Entry Error | Brittany Belcher (b) (4) | 15 Mar 2021 17:24:27 |
| User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. ' (Site from Safety). | (b) (4), (b) (6) | 11 Mar 2021 11:19:53 |
| User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. ' (Site from Safety). | (b) (4), (b) (6) | 08 Mar 2021 16:21:14 |
| User signature succeeded. | Gregory Feldman (b) (4) | 05 Mar 2021 21:40:02 |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:57:13

If not Ongoing, end date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'waiting on records' (Site from Safety). | Wendy Taylor (b) (4) | 05 Mar 2021 19:22:20 |
| User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety). | (b) (4), (b) (6) | 02 Mar 2021 13:53:46 |
| User entered empty. | marsha gossett (b) (4) | 22 Feb 2021 13:44:19 |

US3302105

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:57:13

[End time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 31 Mar 2021 20:50:46 |
| User signature succeeded. | Gregory Feldman (b) (4) | 05 Mar 2021 21:40:02 |
| User entered empty. | marsha gossett (b) (4) | 22 Feb 2021 13:44:19 |

US3302105

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:57:13

[AE End Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 22 Feb 2021 13:44:19 |

US3302105

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:57:13

[Severity](#)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 06 Apr 2021 18:15:51 |
| User closed query 'Please review source and revise if needed. In CRIO AE Page gives the Severity for this SAE as Grade 3, and on AE Version 2 Page lists Grade 2 as the severity for this SAE. Please make sure that severity is the same on all logs and in EDC.' (Site from CRA). | (b) (4), (b) (6) | 06 Apr 2021 18:15:36 |
| Query 'Please review source and revise if needed. In CRIO AE Page gives the Severity for this SAE as Grade 3, and on AE Version 2 Page lists Grade 2 as the severity for this SAE. Please make sure that severity is the same on all logs and in EDC.' answered with 'source updated. ' (Site from CRA). | Brittany Belcher (b) (4) | 06 Apr 2021 18:06:51 |
| User entered 'Grade 3/Severe (Grade 3/Severe)' reason for change: Data Entry Error | Brittany Belcher (b) (4) | 06 Apr 2021 18:06:43 |
| User opened query 'Please review source and revise if needed. In CRIO AE Page gives the Severity for this SAE as Grade 3, and on AE Version 2 Page lists Grade 2 as the severity for this SAE. Please make sure that severity is the same on all logs and in EDC.' (Site from CRA). | (b) (4), (b) (6) | 06 Apr 2021 15:54:13 |
| DataPoint Un-verified. | Brittany Belcher (b) (4) | 05 Apr 2021 19:20:58 |
| Signature has been broken. | Brittany Belcher (b) (4) | 05 Apr 2021 19:20:58 |
| User entered 'Grade 4 (Grade 4)' reason for change: Data Entry Error | Brittany Belcher (b) (4) | 05 Apr 2021 19:20:58 |
| DataPoint Verified. | (b) (4), (b) (6) | 31 Mar 2021 20:50:50 |
| User signature succeeded. | Gregory Feldman (b) (4) | 05 Mar 2021 21:40:02 |
| User entered 'Grade 3/Severe (Grade 3/Severe)' | marsha gossett (b) (4) | 22 Feb 2021 13:44:19 |
| | (b) (4) | |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:57:13

[Is the adverse event serious?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 31 Mar 2021 20:50:52 |
| User signature succeeded. | Gregory Feldman (b) (4) | 05 Mar 2021 21:40:02 |
| User entered 'Yes (Y)' | marsha gossett (b) (4) | 22 Feb 2021 13:44:19 |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:57:13

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 31 Mar 2021 20:50:56 |
| User signature succeeded. | Gregory Feldman (b) (4) | 05 Mar 2021 21:40:02 |
| User entered '0' | marsha gossett (b) (4) | 22 Feb 2021 13:44:19 |

US3302105

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:57:13

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 31 Mar 2021 20:51:02 |
| User signature succeeded. | Gregory Feldman (b) (4) | 05 Mar 2021 21:40:02 |
| User entered '0' | marsha gossett (b) (4) | 22 Feb 2021 13:44:19 |

US3302105

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:57:13

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---|--------------------------|----------------------|
| User closed query 'Per CDM re-query: Thank you for your answer. However, please keep this query open until there is information. Thank you!' (Site from DM). | (b) (4), (b) (6) | 06 Apr 2021 06:06:52 |
| Query 'Per CDM re-query: Thank you for your answer. However, please keep this query open until there is information. Thank you!' answered with 'updated.' (Site from DM). | Brittany Belcher (b) (4) | 05 Apr 2021 21:04:34 |
| DataPoint Verified. | (b) (4), (b) (6) | 31 Mar 2021 20:51:23 |
| User opened query 'Per CDM re-query: Thank you for your answer. However, please keep this query open until there is information. Thank you!' (Site from DM). | (b) (4), (b) (6) | 29 Mar 2021 06:50:27 |
| User closed query 'Per CDM re-query: Thank you for your answer. However, please keep this query open until there is information. Thank you!' (Site from DM). | (b) (4), (b) (6) | 29 Mar 2021 06:50:27 |
| Query 'Per CDM re-query: Thank you for your answer. However, please keep this query open until there is information. Thank you!' answered with 'Sent for medical records. Will complete once received.' (Site from DM). | Brittany Belcher (b) (4) | 26 Mar 2021 13:05:52 |
| User closed query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety). | (b) (4), (b) (6) | 22 Mar 2021 15:32:18 |
| User opened query 'Per CDM re-query: Thank you for your answer. However, please keep this query open until there is information. Thank you!' (Site from DM). | (b) (4), (b) (6) | 22 Mar 2021 09:04:25 |
| User closed query 'Per CDM: Please update "Hospital Discharge Date" once it is available. Thank you!' (Site from DM). | (b) (4), (b) (6) | 22 Mar 2021 09:04:25 |
| Query 'PV Query: Please provide the hospital discharge date when available.' answered with 'RECORDS HAVE BEEN REQUESTED' (Site from Safety). | marsha gossett (b) (4) | 19 Mar 2021 12:36:51 |
| Query 'Per CDM: Please update "Hospital Discharge Date" once it is available. Thank you!' answered with 'RECORDS HAVE BEEN REQUESTED' (Site from DM). | marsha gossett (b) (4) | 19 Mar 2021 12:36:44 |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:57:13

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| User opened query 'PV Query: Please provide the hospital discharge date when available. ' (Site from Safety). | (b) (4), (b) (6) | 11 Mar 2021 11:19:12 |
| User opened query 'Per CDM: Please update "Hospital Discharge Date" once it is available. Thank you!' (Site from DM). | (b) (4), (b) (6) | 08 Mar 2021 08:37:07 |
| User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System). | (b) (4), (b) (6) | 08 Mar 2021 08:36:41 |
| User signature succeeded. | Gregory Feldman (b) (4) | 05 Mar 2021 21:40:02 |
| Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'will update when records are in ' (Site from System). | Wendy Taylor (b) (4) | 05 Mar 2021 19:22:42 |
| User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System). | System | 22 Feb 2021 13:44:19 |
| User entered 'I' | marsha gossett (b) (4) | 22 Feb 2021 13:44:19 |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:57:13

Hospital Admission Date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|--------------------------|----------------------|
| User closed query 'PV Query: Please confirm if the subject was hospitalized overnight as the event was resolved on the same day. If not, please reassess the reported seriousness criterion of hospitalization and determine if any other seriousness criteria were met (i.e. medically significant).' (Site from Safety). | (b) (4), (b) (6) | 06 Apr 2021 14:50:00 |
| Query 'PV Query: Please confirm if the subject was hospitalized overnight as the event was resolved on the same day. If not, please reassess the reported seriousness criterion of hospitalization and determine if any other seriousness criteria were met (i.e. medically significant).' answered with 'updated.' (Site from Safety). | Brittany Belcher (b) (4) | 05 Apr 2021 21:04:40 |
| DataPoint Verified. | (b) (4), (b) (6) | 31 Mar 2021 20:51:28 |
| User opened query 'PV Query: Please confirm if the subject was hospitalized overnight as the event was resolved on the same day. If not, please reassess the reported seriousness criterion of hospitalization and determine if any other seriousness criteria were met (i.e. medically significant).' (Site from Safety). | (b) (4), (b) (6) | 29 Mar 2021 18:10:59 |
| User closed query 'PV Query: Please confirm if the subject was hospitalized overnight as the event was resolved on the same day. If not, please reassess the reported seriousness criterion of hospitalization and determine if any other seriousness criteria were met (i.e. medically significant).' (Site from Safety). | (b) (4), (b) (6) | 29 Mar 2021 18:10:59 |
| Query 'PV Query: Please confirm if the subject was hospitalized overnight as the event was resolved on the same day. If not, please reassess the reported seriousness criterion of hospitalization and determine if any other seriousness criteria were met (i.e. medically significant).' answered with 'Sent for medical records. Will complete once received.' (Site from Safety). | Brittany Belcher (b) (4) | 26 Mar 2021 13:05:28 |
| User opened query 'PV Query: Please confirm if the subject was hospitalized overnight as the event was resolved on the same day. If not, please reassess the reported seriousness criterion of hospitalization and determine if any other seriousness criteria were met (i.e. medically significant).' (Site from Safety). | (b) (4), (b) (6) | 23 Mar 2021 14:01:13 |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:57:13

Hospital Admission Date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 05 Mar 2021 21:40:02 |
| | (b) (4) | |
| User entered '19 Feb 2021' | marsha gossett (b) (4) | 22 Feb 2021 13:44:19 |
| | (b) (4) | |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:57:13

Hospital Discharge Date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 06 Apr 2021 18:18:29 |
| User closed query 'Per Progress Notes in CRIO, it does not state if Medical Records Release Form was completed. In addition, the form was not upload to the subject in CRIO. Was this form ever completed and sent to the Hospital for the records?' (Site from CRA). | (b) (4), (b) (6) | 06 Apr 2021 15:40:46 |
| User closed query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety). | (b) (4), (b) (6) | 06 Apr 2021 14:50:04 |
| Query 'Per Progress Notes in CRIO, it does not state if Medical Records Release Form was completed. In addition, the form was not upload to the subject in CRIO. Was this form ever completed and sent to the Hospital for the records?' answered with 'updated. ' (Site from CRA). | Brittany Belcher (b) (4) | 05 Apr 2021 21:04:46 |
| Query 'PV Query: Please provide the hospital discharge date when available.' answered with 'updated. ' (Site from Safety). | Brittany Belcher (b) (4) | 05 Apr 2021 14:45:56 |
| DataPoint Un-verified. | Brittany Belcher (b) (4) | 05 Apr 2021 14:45:47 |
| Signature has been broken. | Brittany Belcher (b) (4) | 05 Apr 2021 14:45:47 |
| User entered '22 Feb 2021' reason for change: Data Entry Error | Brittany Belcher (b) (4) | 05 Apr 2021 14:45:47 |
| User opened query 'Per Progress Notes in CRIO, it does not state if Medical Records Release Form was completed. In addition, the form was not upload to the subject in CRIO. Was this form ever completed and sent to the Hospital for the records?' (Site from CRA). | (b) (4), (b) (6) | 31 Mar 2021 20:58:09 |
| DataPoint Verified. | (b) (4), (b) (6) | 31 Mar 2021 20:51:36 |
| User opened query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety). | (b) (4), (b) (6) | 29 Mar 2021 18:11:04 |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:57:13

Hospital Discharge Date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|--------------------------|----------------------|
| User closed query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety). | (b) (4), (b) (6) | 29 Mar 2021 18:11:04 |
| Query 'PV Query: Please provide the hospital discharge date when available.' answered with 'Sent for medical records. Will complete once received.' (Site from Safety). | Brittany Belcher (b) (4) | 26 Mar 2021 13:05:40 |
| User opened query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety). | (b) (4), (b) (6) | 23 Mar 2021 13:59:58 |
| User closed query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety). | (b) (4), (b) (6) | 08 Mar 2021 16:21:11 |
| User signature succeeded. | Gregory Feldman (b) (4) | 05 Mar 2021 21:40:02 |
| Query 'PV Query: Please provide the hospital discharge date when available.' answered with 'will update when records are in ' (Site from Safety). | Wendy Taylor (b) (4) | 05 Mar 2021 19:23:00 |
| User opened query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety). | (b) (4), (b) (6) | 02 Mar 2021 13:53:09 |
| User entered empty. | marsha gossett (b) (4) | 22 Feb 2021 13:44:19 |

US3302105

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:57:13

[Admitted to ICU?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 31 Mar 2021 20:51:39 |
| User signature succeeded. | Gregory Feldman (b) (4) | 05 Mar 2021 21:40:02 |
| User entered 'No (N)' | marsha gossett (b) (4) | 22 Feb 2021 13:44:19 |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:57:13

[Number of Days in ICU](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 31 Mar 2021 20:51:40 |
| User signature succeeded. | Gregory Feldman (b) (4) | 05 Mar 2021 21:40:02 |
| User entered empty. | marsha gossett (b) (4) | 22 Feb 2021 13:44:19 |

US3302105

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:57:13

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 31 Mar 2021 20:51:43 |
| User signature succeeded. | Gregory Feldman (b) (4) | 05 Mar 2021 21:40:02 |
| User entered '0' | marsha gossett (b) (4) | 22 Feb 2021 13:44:19 |

US3302105

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:57:13

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 31 Mar 2021 20:51:46 |
| User signature succeeded. | Gregory Feldman (b) (4) | 05 Mar 2021 21:40:02 |
| User entered '0' | marsha gossett (b) (4) | 22 Feb 2021 13:44:19 |

US3302105

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:57:13

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 31 Mar 2021 20:51:48 |
| User signature succeeded. | Gregory Feldman (b) (4) | 05 Mar 2021 21:40:02 |
| User entered '0' | marsha gossett (b) (4) | 22 Feb 2021 13:44:19 |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:57:13

[Relationship to investigational product](#)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 31 Mar 2021 20:51:51 |
| User signature succeeded. | Gregory Feldman (b) (4) | 05 Mar 2021 21:40:02 |
| User entered 'Not Related (NOT RELATED)' | marsha gossett (b) (4) | 22 Feb 2021 13:44:19 |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:57:13

[Relationship to Study Procedure](#)

| Audit | User | Time (GMT) |
|--|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 31 Mar 2021 20:51:53 |
| User signature succeeded. | Gregory Feldman (b) (4) | 05 Mar 2021 21:40:02 |
| User entered 'Not Related (NOT RELATED)' | marsha gossett (b) (4) | 22 Feb 2021 13:44:19 |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:57:13

Action taken with investigational product

| Audit | User | Time (GMT) |
|---|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 31 Mar 2021 20:51:54 |
| User closed query 'PV Query: As the subject received both doses of mRNA-1273 prior to the onset of the event, please consider updating the action taken to not applicable.' (Site from Safety). | (b) (4), (b) (6) | 08 Mar 2021 16:21:09 |
| User signature succeeded. | Gregory Feldman (b) (4) | 05 Mar 2021 21:40:02 |
| Query 'PV Query: As the subject received both doses of mRNA-1273 prior to the onset of the event, please consider updating the action taken to not applicable.' | Wendy Taylor (b) (4) | 05 Mar 2021 19:23:40 |
| answered with 'updated ' (Site from Safety). | | |
| User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error | Wendy Taylor (b) (4) | 05 Mar 2021 19:23:30 |
| User opened query 'PV Query: As the subject received both doses of mRNA-1273 prior to the onset of the event, please consider updating the action taken to not applicable.' (Site from Safety). | (b) (4), (b) (6) | 02 Mar 2021 13:52:39 |
| User entered 'None (NONE)' | marsha gossett (b) (4) | 22 Feb 2021 13:44:19 |

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Folder: Adverse Events

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Generated On: 09 Jun 2021 16:57:13

None

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| User closed query 'Per CDM CLR re-query: Thank you for your answer. However, please be aware that there is no CM recorded regarding this AE. There is recorded vitamin for this AE, however no actual medication. Please review and update or clarify otherwise. Thank you!' (Site from DM). | (b) (4) (b) (4), (b) (6) | 15 Apr 2021 02:58:46 |
| Query 'Per CDM CLR re-query: Thank you for your answer. However, please be aware that there is no CM recorded regarding this AE. There is recorded vitamin for this AE, however no actual medication. Please review and update or clarify otherwise. Thank you!' answered with 'updated. ' (Site from DM). | Brittany Belcher (b) (4) | 14 Apr 2021 12:27:19 |
| User entered '1' reason for change: Data Entry Error | Brittany Belcher (b) (4) | 14 Apr 2021 12:27:03 |
| User entered '0' reason for change: Data Entry Error | Brittany Belcher (b) (4) | 13 Apr 2021 12:18:03 |
| DataPoint Un-verified. | Brittany Belcher (b) (4) | 13 Apr 2021 12:17:33 |
| User entered '1' reason for change: Data Entry Error | Brittany Belcher (b) (4) | 13 Apr 2021 12:17:33 |
| DataPoint Verified. | (b) (4), (b) (6) | 06 Apr 2021 15:40:32 |
| User opened query 'Per CDM CLR re-query: Thank you for your answer. However, please be aware that there is no CM recorded regarding this AE. There is recorded vitamin for this AE, however no actual medication. Please review and update or clarify otherwise. Thank you!' (Site from DM). | (b) (4), (b) (6) | 06 Apr 2021 06:08:58 |
| User closed query 'Per CDM CLR re-query: Thank you for your answer. However, please keep this query open until there is information. Thank you! ' (Site from DM). | (b) (4), (b) (6) | 06 Apr 2021 06:08:58 |
| Query 'Per CDM CLR re-query: Thank you for your answer. However, please keep this query open until there is information. Thank you! ' answered with 'updated. ' (Site from DM). | Brittany Belcher (b) (4) | 05 Apr 2021 14:46:18 |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:57:13

None

| Audit | User | Time (GMT) |
|---|--------------------------|----------------------|
| DataPoint Un-verified. | Brittany Belcher (b) (4) | 05 Apr 2021 14:45:47 |
| | | |
| Signature has been broken. | Brittany Belcher (b) (4) | 05 Apr 2021 14:45:47 |
| | | |
| User entered '0' reason for change: Data Entry Error | Brittany Belcher (b) (4) | 05 Apr 2021 14:45:47 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 31 Mar 2021 20:52:03 |
| User opened query 'Per CDM CLR re-query: Thank you for your answer. However, please keep this query open until there is information. Thank you! ' (Site from DM). | (b) (4), (b) (6) | 29 Mar 2021 06:50:51 |
| User closed query 'Per DM CLR: Serious= YES. However, there is no CM/ConProc recorded during the hospitalization period, and treatment is expected. Please review and ensure that CM/ConProc performed for this serious condition is added in the appropriate eCRFs. Update as applicable. Otherwise, provide comment for no treatment given. ' (Site from DM). | (b) (4), (b) (6) | 29 Mar 2021 06:50:51 |
| Query 'Per DM CLR: Serious= YES. However, there is no CM/ConProc recorded during the hospitalization period, and treatment is expected. Please review and ensure that CM/ConProc performed for this serious condition is added in the appropriate eCRFs. Update as applicable. Otherwise, provide comment for no treatment given. ' answered with 'Sent for medical records. Will complete once received. ' (Site from DM). | Brittany Belcher (b) (4) | 26 Mar 2021 13:06:46 |
| User opened query 'Per DM CLR: Serious= YES. However, there is no CM/ConProc recorded during the hospitalization period, and treatment is expected. Please review and ensure that CM/ConProc performed for this serious condition is added in the appropriate eCRFs. Update as applicable. Otherwise, provide comment for no treatment given. ' (Site from DM). | (b) (4), (b) (6) | 23 Mar 2021 03:34:08 |
| User signature succeeded. | Gregory Feldman (b) (4) | 05 Mar 2021 21:40:02 |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:57:13

None

| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System). | System | 05 Mar 2021 19:24:59 |
| User entered '1' reason for change: Data Entry Error | Wendy Taylor (b) (4) | 05 Mar 2021 19:24:59 |
| | | |
| User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System). | System | 22 Feb 2021 13:44:19 |
| User entered '0' | marsha gossett (b) (4) | 22 Feb 2021 13:44:19 |
| | (b) (4) | |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:57:13

[Concomitant Medication](#)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| | (b) (4) | |
| User entered '0' reason for change: Data Entry Error | Brittany Belcher (b) (4) | 14 Apr 2021 12:27:03 |
| | | |
| User entered '1' reason for change: Data Entry Error | Brittany Belcher (b) (4) | 13 Apr 2021 12:18:03 |
| | | |
| DataPoint Un-verified. | Brittany Belcher (b) (4) | 13 Apr 2021 12:17:33 |
| | | |
| User entered '0' reason for change: Data Entry Error | Brittany Belcher (b) (4) | 13 Apr 2021 12:17:33 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 06 Apr 2021 15:39:52 |
| | | |
| DataPoint Un-verified. | Brittany Belcher (b) (4) | 05 Apr 2021 14:45:47 |
| | | |
| Signature has been broken. | Brittany Belcher (b) (4) | 05 Apr 2021 14:45:47 |
| | | |
| User entered '1' reason for change: Data Entry Error | Brittany Belcher (b) (4) | 05 Apr 2021 14:45:47 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 31 Mar 2021 20:52:06 |
| | | |
| User signature succeeded. | Gregory Feldman (b) (4) | 05 Mar 2021 21:40:02 |
| | (b) (4) | |
| User entered '0' | marsha gossett (b) (4) | 22 Feb 2021 13:44:19 |
| | (b) (4) | |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:57:13

[Concomitant Procedure](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 31 Mar 2021 20:52:08 |
| User signature succeeded. | Gregory Feldman (b) (4) | 05 Mar 2021 21:40:02 |
| User entered '0' | marsha gossett (b) (4) | 22 Feb 2021 13:44:19 |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:57:13

[Outcome](#)

| Audit | User | Time (GMT) |
|---|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 31 Mar 2021 20:52:10 |
| Query ' PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' canceled (Site from Safety). | (b) (4), (b) (6) | 29 Mar 2021 18:13:01 |
| User opened query ' PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety). | (b) (4), (b) (6) | 29 Mar 2021 18:11:12 |
| User closed query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved. | (b) (4), (b) (6) | 29 Mar 2021 18:11:12 |
| ' (Site from Safety). | | |
| Query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved. | Brittany Belcher (b) (4) | 26 Mar 2021 13:06:59 |
| ' answered with 'Sent for medical records. Will complete once received. ' (Site from Safety). | | |
| Signature has been broken. | Brittany Belcher (b) (4) | 15 Mar 2021 17:24:55 |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error | Brittany Belcher (b) (4) | 15 Mar 2021 17:24:55 |
| User opened query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved. | (b) (4), (b) (6) | 11 Mar 2021 11:20:56 |
| ' (Site from Safety). | | |
| User closed query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety). | (b) (4), (b) (6) | 08 Mar 2021 16:21:08 |
| User signature succeeded. | Gregory Feldman (b) (4) | 05 Mar 2021 21:40:02 |
| | (b) (4) | |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:57:13

[Outcome](#)

| Audit | User | Time (GMT) |
|---|------------------------|----------------------|
| Query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' answered with 'will update when records are in ' (Site from Safety). | Wendy Taylor (b) (4) | 05 Mar 2021 19:24:19 |
| User opened query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety). | (b) (4), (b) (6) | 02 Mar 2021 13:54:13 |
| User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' | marsha gossett (b) (4) | 22 Feb 2021 13:44:19 |

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Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:57:13

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 31 Mar 2021 20:52:14 |
| User signature succeeded. | Gregory Feldman (b) (4) | 05 Mar 2021 21:40:02 |
| User entered empty. | marsha gossett (b) (4) | 22 Feb 2021 13:44:19 |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:57:13

[Narrative](#)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| User closed query 'PV query: Please consider whether cardiomyopathy and reduced ejection fraction as noted in medical records meet AE/SAE reporting criteria and update report if appropriate.' (Site from Safety). | (b) (4), (b) (6) | 16 Apr 2021 13:21:04 |
| User closed query 'PV Query: Vitamin D indication was reported as SAE. Please clarify and update.' (Site from Safety). | (b) (4), (b) (6) | 16 Apr 2021 13:21:00 |
| Query 'PV query: Please consider whether cardiomyopathy and reduced ejection fraction as noted in medical records meet AE/SAE reporting criteria and update report if appropriate.' answered with 'Per PI, Cardiomyopathy is secondary to the MI.' (Site from Safety). | Brittany Belcher (b) (4) | 15 Apr 2021 16:11:31 |
| Query 'PV Query: Vitamin D indication was reported as SAE. Please clarify and update.' answered with 'Vitamin D is not a SAE/AE.' (Site from Safety). | Brittany Belcher (b) (4) | 15 Apr 2021 16:09:40 |
| User opened query 'PV query: Please consider whether cardiomyopathy and reduced ejection fraction as noted in medical records meet AE/SAE reporting criteria and update report if appropriate.' (Site from Safety). | (b) (4), (b) (6) | 15 Apr 2021 14:13:10 |
| User opened query 'PV Query: Vitamin D indication was reported as SAE. Please clarify and update.' (Site from Safety). | (b) (4), (b) (6) | 15 Apr 2021 14:12:44 |
| DataPoint Verified. | (b) (4), (b) (6) | 06 Apr 2021 15:40:18 |
| User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety). | (b) (4), (b) (6) | 06 Apr 2021 14:50:23 |
| User closed query ' PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety). | (b) (4), (b) (6) | 06 Apr 2021 14:50:18 |

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (2)

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[Narrative](#)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| User closed query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety). | (b) (4), (b) (6) | 06 Apr 2021 14:50:12 |
| Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' answered with 'updated. ' (Site from Safety). | Brittany Belcher (b) (4) | 05 Apr 2021 21:05:37 |
| Query ' PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'updated. ' (Site from Safety). | Brittany Belcher (b) (4) | 05 Apr 2021 21:05:31 |
| Query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' answered with 'updated. ' (Site from Safety). | Brittany Belcher (b) (4) | 05 Apr 2021 21:05:25 |
| Signature has been broken. | Brittany Belcher (b) (4) | 05 Apr 2021 21:05:18 |
| User entered 'SPOUSE CALLED STATING WIFE SUFFERED AN MI WHILE ON VACATION SNOW SKIING, SPOUSE STATES WIFE IS FINE, HAD NO BLOCKAGES AND THEY'RE UNSURE WHY MI OCCURRED. 4/5/2021: Subject's medical records regarding previously reported SAE has been received/reviewed. All Con Meds, Medical History, and Con Procedures lists updated in source and EDC. IRB was updated after review.' reason for change: Data Entry Error | Brittany Belcher (b) (4) | 05 Apr 2021 21:05:18 |

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (2)

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| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| DataPoint Un-verified. | (b) (4), (b) (6) | 31 Mar 2021 20:52:21 |
| DataPoint Verified. | (b) (4), (b) (6) | 31 Mar 2021 20:52:17 |
| User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety). | (b) (4), (b) (6) | 29 Mar 2021 18:11:31 |
| User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety). | (b) (4), (b) (6) | 29 Mar 2021 18:11:31 |
| User opened query ' PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety). | (b) (4), (b) (6) | 29 Mar 2021 18:11:24 |
| User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety). | (b) (4), (b) (6) | 29 Mar 2021 18:11:24 |
| User opened query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety). | (b) (4), (b) (6) | 29 Mar 2021 18:11:18 |

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| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| User closed query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety). | (b) (4), (b) (6) | 29 Mar 2021 18:11:18 |
| Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' answered with 'Sent for medical records. Will complete once received. ' (Site from Safety). | Brittany Belcher (b) (4) | 26 Mar 2021 13:07:32 |
| Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'Sent for medical records. Will complete once received. ' (Site from Safety). | Brittany Belcher (b) (4) | 26 Mar 2021 13:07:21 |
| Query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' answered with 'Sent for medical records. Will complete once received. ' (Site from Safety). | Brittany Belcher (b) (4) | 26 Mar 2021 13:07:11 |
| User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety). | (b) (4), (b) (6) | 23 Mar 2021 14:00:47 |

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[Narrative](#)

| Audit | User | Time (GMT) |
|---|-----------------------------------|----------------------|
| User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety). | (b) (4), (b) (6) | 23 Mar 2021 14:00:29 |
| User opened query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety). | (b) (4), (b) (6) | 23 Mar 2021 13:59:34 |
| User closed query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' (Site from Safety). | (b) (4), (b) (6) | 22 Mar 2021 15:32:27 |
| User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so. ' (Site from Safety). | (b) (4), (b) (6) | 22 Mar 2021 15:32:24 |
| Query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' answered with 'RECORDS HAVE BEEN REQUESTED' (Site from Safety). | marsha gossett (b) (4) (b) (4) | 19 Mar 2021 12:37:28 |

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| Audit | User | Time (GMT) |
|---|-------------------------|----------------------|
| Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so. ' answered with 'RECORDS HAVE BEEN REQUESTED' (Site from Safety). | marsha gossett (b) (4) | 19 Mar 2021 12:37:17 |
| User opened query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' (Site from Safety). | (b) (4), (b) (6) | 11 Mar 2021 11:21:50 |
| User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so. ' (Site from Safety). | (b) (4), (b) (6) | 11 Mar 2021 11:21:16 |
| User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety). | (b) (4), (b) (6) | 08 Mar 2021 16:21:05 |
| User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response' (Site from Safety). | (b) (4), (b) (6) | 08 Mar 2021 16:21:04 |
| User signature succeeded. | Gregory Feldman (b) (4) | 05 Mar 2021 21:40:02 |

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| Audit | User | Time (GMT) |
|--|------------------------|----------------------|
| Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response' answered with 'will update when records are in ' (Site from Safety). | Wendy Taylor (b) (4) | 05 Mar 2021 19:24:36 |
| Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'will update when records are in ' (Site from Safety). | Wendy Taylor (b) (4) | 05 Mar 2021 19:24:30 |
| User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response' (Site from Safety). | (b) (4), (b) (6) | 02 Mar 2021 13:54:47 |
| User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety). | (b) (4), (b) (6) | 02 Mar 2021 13:54:30 |
| User entered 'spouse called stating wife suffered an MI while on vacation snow skiing, spouse states wife is fine, had no blockages and they're unsure why MI occurred.' | marsha gossett (b) (4) | 22 Feb 2021 13:44:19 |

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Form: Adverse Events (2)

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[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 22 Feb 2021 13:44:19 |

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Folder: Adverse Events

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[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 22 Feb 2021 13:44:19 |

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Folder: Adverse Events

Form: Adverse Events (2)

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[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '0' | System | 22 Feb 2021 13:44:19 |

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:57:13

[Adverse event](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| | (b) (4) | |
| User coded data point as SOC: Cardiac disorders, HLGT: Myocardial disorders, HLT: Cardiomyopathies, PT: Cardiomyopathy, LLT: Cardiomyopathy - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 05 Apr 2021 14:54:35 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 05 Apr 2021 14:54:35 |
| Data point term sent to Coder | System | 05 Apr 2021 14:52:52 |
| User entered 'Cardiomyopathy' | Brittany Belcher (b) (4) | 05 Apr 2021 14:52:19 |
| | | |
| | | |

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:57:13

[Was this a medically-attended AE?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Brittany Belcher (b) (4) | 05 Apr 2021 14:52:19 |
| | | |
| | | |

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:57:13

[Was this a Solicited Adverse Reaction?](#)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| | (b) (4) | |
| User entered 'No (N)' reason for change: Data Entry Error | Brittany Belcher (b) (4) | 05 Apr 2021 19:24:48 |
| | | |
| User entered 'Yes (Y)' reason for change: Data Entry Error | Brittany Belcher (b) (4) | 05 Apr 2021 19:21:37 |
| | | |
| User entered 'No (N)' | Brittany Belcher (b) (4) | 05 Apr 2021 14:52:19 |
| | | |
| | | |

US3302105

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:57:13

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| | (b) (4) | |
| User entered 'No (N)' | Brittany Belcher (b) (4) | 05 Apr 2021 14:52:19 |
| | | |
| | | |

US3302105

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:57:13

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| | (b) (4) | |
| User entered '22 Feb 2021' | Brittany Belcher (b) (4) | 05 Apr 2021 14:52:19 |
| | | |
| | | |

US3302105

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:57:13

[Start time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| | (b) (4) | |
| User entered empty. | Brittany Belcher (b) (4) | 05 Apr 2021 14:52:19 |
| | | |
| | | |

US3302105

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:57:13

[AE start date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 05 Apr 2021 14:52:19 |

US3302105

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:57:13

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Brittany Belcher (b) (4) | 05 Apr 2021 14:52:19 |
| | | |
| | | |

US3302105

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:57:13

If not Ongoing, end date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| | (b) (4) | |
| User entered empty. | Brittany Belcher (b) (4) | 05 Apr 2021 14:52:19 |
| | | |
| | | |

US3302105

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:57:13

End time (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| | (b) (4) | |
| User entered empty. | Brittany Belcher (b) (4) | 05 Apr 2021 14:52:19 |
| | | |
| | | |

US3302105

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:57:13

[AE End Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 05 Apr 2021 14:52:19 |

US3302105

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:57:13

[Severity](#)

| Audit | User | Time (GMT) |
|--|-------------------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| User entered 'Grade 2/Moderate (Grade 2/Moderate)' reason for change: Data Entry Error | (b) (4) Brittany Belcher (b) (4) | 05 Apr 2021 19:24:48 |
| User entered 'Grade 4 (Grade 4)' reason for change: Data Entry Error | Brittany Belcher (b) (4) | 05 Apr 2021 19:21:17 |
| User entered 'Grade 2/Moderate (Grade 2/Moderate)' | Brittany Belcher (b) (4) | 05 Apr 2021 14:52:19 |

US3302105

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:57:13

[Is the adverse event serious?](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| User closed query 'AE severity is Grade 4, but is the adverse event serious is No. Please confirm or correct.' (Site from System). | (b) (4) (b) (4), (b) (6) | 06 Apr 2021 06:09:44 |
| Query 'AE severity is Grade 4, but is the adverse event serious is No. Please confirm or correct.' answered with 'updated. ' (Site from System). | Brittany Belcher (b) (4) | 05 Apr 2021 19:21:44 |
| User opened query 'AE severity is Grade 4, but is the adverse event serious is No. Please confirm or correct.' (Site from System). | System | 05 Apr 2021 19:21:17 |
| User entered 'No (N)' | Brittany Belcher (b) (4) | 05 Apr 2021 14:52:19 |

US3302105

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:57:13

Death

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| | (b) (4) | |
| User entered '0' | Brittany Belcher (b) (4) | 05 Apr 2021 14:52:19 |
| | | |
| | | |

US3302105

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:57:13

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| | (b) (4) | |
| User entered '0' | Brittany Belcher (b) (4) | 05 Apr 2021 14:52:19 |
| | | |
| | | |

US3302105

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:57:13

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| | (b) (4) | |
| User entered '0' | Brittany Belcher (b) (4) | 05 Apr 2021 14:52:19 |
| | | |
| | | |

US3302105

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:57:13

Hospital Admission Date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| | (b) (4) | |
| User entered empty. | Brittany Belcher (b) (4) | 05 Apr 2021 14:52:19 |
| | | |
| | | |

US3302105

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:57:13

Hospital Discharge Date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| | (b) (4) | |
| User entered empty. | Brittany Belcher (b) (4) | 05 Apr 2021 14:52:19 |
| | | |
| | | |

US3302105

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:57:13

[Admitted to ICU?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| | (b) (4) | |
| User entered empty. | Brittany Belcher (b) (4) | 05 Apr 2021 14:52:19 |
| | | |
| | | |

US3302105

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:57:13

[Number of Days in ICU](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| | (b) (4) | |
| User entered empty. | Brittany Belcher (b) (4) | 05 Apr 2021 14:52:19 |
| | | |
| | | |

US3302105

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:57:13

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| | (b) (4) | |
| User entered '0' | Brittany Belcher (b) (4) | 05 Apr 2021 14:52:19 |
| | | |
| | | |

US3302105

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:57:13

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| | (b) (4) | |
| User entered '0' | Brittany Belcher (b) (4) | 05 Apr 2021 14:52:19 |
| | | |
| | | |

US3302105

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:57:13

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| | (b) (4) | |
| User entered '0' | Brittany Belcher (b) (4) | 05 Apr 2021 14:52:19 |
| | | |
| | | |

US3302105

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:57:13

[Relationship to investigational product](#)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| | (b) (4) | |
| User entered 'Not Related (NOT RELATED)' | Brittany Belcher (b) (4) | 05 Apr 2021 14:52:19 |
| | | |
| | | |

US3302105

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:57:13

[Relationship to Study Procedure](#)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| | (b) (4) | |
| User entered 'Not Related (NOT RELATED)' | Brittany Belcher (b) (4) | 05 Apr 2021 14:52:19 |
| | | |
| | | |

US3302105

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:57:13

[Action taken with investigational product](#)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| | (b) (4) | |
| User entered 'Not Applicable (NOT APPLICABLE)' | Brittany Belcher (b) (4) | 05 Apr 2021 14:52:19 |
| | | |
| | | |

US3302105

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:57:13

None

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| | (b) (4) | |
| User entered 'I' | Brittany Belcher (b) (4) | 05 Apr 2021 14:52:19 |
| | | |
| | | |

US3302105

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:57:13

[Concomitant Medication](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| | (b) (4) | |
| User entered '0' | Brittany Belcher (b) (4) | 05 Apr 2021 14:52:19 |
| | | |
| | | |

US3302105

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:57:13

[Concomitant Procedure](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| | (b) (4) | |
| User entered '0' | Brittany Belcher (b) (4) | 05 Apr 2021 14:52:19 |
| | | |
| | | |

US3302105

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:57:13

[Outcome](#)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| | (b) (4) | |
| User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' | Brittany Belcher (b) (4) | 05 Apr 2021 14:52:19 |
| | | |
| | | |

US3302105

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:57:13

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| | (b) (4) | |
| User entered empty. | Brittany Belcher (b) (4) | 05 Apr 2021 14:52:19 |
| | | |
| | | |

US3302105

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:57:13

[Narrative](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| | (b) (4) | |
| User entered empty. | Brittany Belcher (b) (4) | 05 Apr 2021 14:52:19 |
| | | |
| | | |

US3302105

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:57:13

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '0' | System | 05 Apr 2021 14:52:19 |

US3302105

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:57:13

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 05 Apr 2021 14:52:19 |

US3302105

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:57:13

[Adverse event](#)

| Audit | User | Time (GMT) |
|---|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| | (b) (4) | |
| User coded data point as SOC: Cardiac disorders, HLGT: Heart failures, HLT: Heart failures NEC, PT: Cardiac failure congestive, LLT: Congestive heart failure - version MedDRA\\23.0. | Coder Import (b) (4) | 05 Apr 2021 14:54:36 |
| | (b) (4) | |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 05 Apr 2021 14:54:36 |
| | (b) (4) | |
| Data point term sent to Coder | System | 05 Apr 2021 14:53:55 |
| User entered 'Congestive Heart Failure' | Brittany Belcher (b) (4) | 05 Apr 2021 14:53:01 |
| | | |
| | | |

US3302105

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:57:13

[Was this a medically-attended AE?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Brittany Belcher (b) (4) | 05 Apr 2021 14:53:01 |
| | | |
| | | |

US3302105

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:57:13

[Was this a Solicited Adverse Reaction?](#)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| | (b) (4) | |
| User entered 'No (N)' reason for change: Data Entry Error | Brittany Belcher (b) (4) | 05 Apr 2021 19:22:22 |
| | | |
| User entered 'Yes (Y)' reason for change: Data Entry Error | Brittany Belcher (b) (4) | 05 Apr 2021 19:22:04 |
| | | |
| User entered 'No (N)' | Brittany Belcher (b) (4) | 05 Apr 2021 14:53:01 |
| | | |
| | | |

US3302105

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:57:13

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| | (b) (4) | |
| User entered 'No (N)' | Brittany Belcher (b) (4) | 05 Apr 2021 14:53:01 |
| | | |
| | | |

US3302105

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:57:13

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| | (b) (4) | |
| User entered '22 Feb 2021' | Brittany Belcher (b) (4) | 05 Apr 2021 14:53:01 |
| | | |
| | | |

US3302105

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:57:13

Start time (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| | (b) (4) | |
| User entered empty. | Brittany Belcher (b) (4) | 05 Apr 2021 14:53:01 |
| | | |
| | | |

US3302105

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:57:13

[AE start date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 05 Apr 2021 14:53:01 |

US3302105

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:57:13

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Brittany Belcher (b) (4) | 05 Apr 2021 14:53:01 |
| | | |
| | | |

US3302105

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:57:13

If not Ongoing, end date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| | (b) (4) | |
| User entered empty. | Brittany Belcher (b) (4) | 05 Apr 2021 14:53:01 |
| | | |
| | | |

US3302105

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:57:13

End time (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| | (b) (4) | |
| User entered empty. | Brittany Belcher (b) (4) | 05 Apr 2021 14:53:01 |
| | | |
| | | |

US3302105

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:57:13

[AE End Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 05 Apr 2021 14:53:01 |

US3302105

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:57:13

[Severity](#)

| Audit | User | Time (GMT) |
|--|-------------------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| User entered 'Grade 2/Moderate (Grade 2/Moderate)' reason for change: Data Entry Error | (b) (4) Brittany Belcher (b) (4) | 05 Apr 2021 19:24:30 |
| User entered 'Grade 4 (Grade 4)' reason for change: Data Entry Error | Brittany Belcher (b) (4) | 05 Apr 2021 19:22:04 |
| User entered 'Grade 2/Moderate (Grade 2/Moderate)' | Brittany Belcher (b) (4) | 05 Apr 2021 14:53:01 |

US3302105

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:57:13

[Is the adverse event serious?](#)

| Audit | User | Time (GMT) |
|--|-------------------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System). | (b) (4) System | 05 Apr 2021 19:24:30 |
| User entered 'No (N)' reason for change: Data Entry Error | Brittany Belcher (b) (4) (b) (4) | 05 Apr 2021 19:24:30 |
| User closed query 'AE severity is Grade 4, but is the adverse event serious is No. Please confirm or correct.' (Site from System). | System | 05 Apr 2021 19:22:22 |
| Query 'AE severity is Grade 4, but is the adverse event serious is No. Please confirm or correct.' answered by data change (Site from System). | System | 05 Apr 2021 19:22:22 |
| User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System). | System | 05 Apr 2021 19:22:22 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | Brittany Belcher (b) (4) (b) (4) | 05 Apr 2021 19:22:22 |
| User opened query 'AE severity is Grade 4, but is the adverse event serious is No. Please confirm or correct.' (Site from System). | System | 05 Apr 2021 19:22:04 |
| User entered 'No (N)' | Brittany Belcher (b) (4) (b) (4) | 05 Apr 2021 14:53:01 |

US3302105

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:57:13

Death

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| | (b) (4) | |
| User entered '0' | Brittany Belcher (b) (4) | 05 Apr 2021 14:53:01 |
| | | |
| | | |

US3302105

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:57:13

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| | (b) (4) | |
| User entered '0' | Brittany Belcher (b) (4) | 05 Apr 2021 14:53:01 |
| | | |
| | | |

US3302105

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:57:13

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| | (b) (4) | |
| User entered '0' | Brittany Belcher (b) (4) | 05 Apr 2021 14:53:01 |
| | | |
| | | |

US3302105

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:57:13

Hospital Admission Date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| | (b) (4) | |
| User entered empty. | Brittany Belcher (b) (4) | 05 Apr 2021 14:53:01 |
| | | |
| | | |

US3302105

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:57:13

Hospital Discharge Date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| | (b) (4) | |
| User entered empty. | Brittany Belcher (b) (4) | 05 Apr 2021 14:53:01 |
| | | |
| | | |

US3302105

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:57:13

[Admitted to ICU?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| | (b) (4) | |
| User entered empty. | Brittany Belcher (b) (4) | 05 Apr 2021 14:53:01 |
| | | |
| | | |

US3302105

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:57:13

[Number of Days in ICU](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| | (b) (4) | |
| User entered empty. | Brittany Belcher (b) (4) | 05 Apr 2021 14:53:01 |
| | | |
| | | |

US3302105

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:57:13

Persistent or significant disability or incapacity

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| | (b) (4) | |
| User entered '0' | Brittany Belcher (b) (4) | 05 Apr 2021 14:53:01 |
| | | |
| | | |

US3302105

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:57:13

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| | (b) (4) | |
| User entered '0' | Brittany Belcher (b) (4) | 05 Apr 2021 14:53:01 |
| | | |
| | | |

US3302105

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:57:13

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| | (b) (4) | |
| User entered '0' | Brittany Belcher (b) (4) | 05 Apr 2021 14:53:01 |
| | | |
| | | |

US3302105

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:57:13

[Relationship to investigational product](#)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| | (b) (4) | |
| User entered 'Not Related (NOT RELATED)' | Brittany Belcher (b) (4) | 05 Apr 2021 14:53:01 |
| | | |
| | | |

US3302105

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:57:13

[Relationship to Study Procedure](#)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| | (b) (4) | |
| User entered 'Not Related (NOT RELATED)' | Brittany Belcher (b) (4) | 05 Apr 2021 14:53:01 |
| | | |
| | | |

US3302105

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:57:13

[Action taken with investigational product](#)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| | (b) (4) | |
| User entered 'Not Applicable (NOT APPLICABLE)' | Brittany Belcher (b) (4) | 05 Apr 2021 14:53:01 |
| | | |
| | | |

US3302105

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:57:13

None

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| | (b) (4) | |
| User entered '0' | Brittany Belcher (b) (4) | 05 Apr 2021 14:53:01 |
| | | |
| | | |

US3302105

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:57:13

[Concomitant Medication](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| | (b) (4) | |
| User entered 'I' | Brittany Belcher (b) (4) | 05 Apr 2021 14:53:01 |
| | | |
| | | |

US3302105

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:57:13

[Concomitant Procedure](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| | (b) (4) | |
| User entered '0' | Brittany Belcher (b) (4) | 05 Apr 2021 14:53:01 |
| | | |
| | | |

US3302105

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:57:13

[Outcome](#)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| | (b) (4) | |
| User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' | Brittany Belcher (b) (4) | 05 Apr 2021 14:53:01 |
| | | |
| | | |

US3302105

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:57:13

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| | (b) (4) | |
| User entered empty. | Brittany Belcher (b) (4) | 05 Apr 2021 14:53:01 |
| | | |
| | | |

US3302105

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:57:13

[Narrative](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| | (b) (4) | |
| User entered empty. | Brittany Belcher (b) (4) | 05 Apr 2021 14:53:01 |
| | | |
| | | |

US3302105

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:57:13

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '0' | System | 05 Apr 2021 19:24:30 |
| User entered '1' | System | 05 Apr 2021 19:22:22 |
| User entered '0' | System | 05 Apr 2021 14:53:01 |

US3302105

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:57:13

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 05 Apr 2021 14:53:01 |

US3302105

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:57:13

[Adverse event](#)

| Audit | User | Time (GMT) |
|---|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| | (b) (4) | |
| User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Hyperlipidaemias NEC, PT: Hyperlipidaemia, LLT: Hyperlipidemia - version MedDRA\\23.0. | Coder Import (b) (4) | 05 Apr 2021 14:54:36 |
| | (b) (4) | |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 05 Apr 2021 14:54:36 |
| | (b) (4) | |
| Data point term sent to Coder | System | 05 Apr 2021 14:53:55 |
| User entered 'Hyperlipidemia' | Brittany Belcher (b) (4) | 05 Apr 2021 14:53:43 |
| | | |
| | | |

US3302105

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:57:13

[Was this a medically-attended AE?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Brittany Belcher (b) (4) | 05 Apr 2021 14:53:43 |
| | | |
| | | |

US3302105

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:57:13

[Was this a Solicited Adverse Reaction?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| | (b) (4) | |
| User entered 'No (N)' | Brittany Belcher (b) (4) | 05 Apr 2021 14:53:43 |
| | | |
| | | |

US3302105

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:57:13

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| | (b) (4) | |
| User entered 'No (N)' | Brittany Belcher (b) (4) | 05 Apr 2021 14:53:43 |
| | | |
| | | |

US3302105

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:57:13

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| | (b) (4) | |
| User entered '20 Feb 2021' | Brittany Belcher (b) (4) | 05 Apr 2021 14:53:43 |
| | | |
| | | |

US3302105

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:57:13

Start time (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| | (b) (4) | |
| User entered empty. | Brittany Belcher (b) (4) | 05 Apr 2021 14:53:43 |
| | | |
| | | |

US3302105

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:57:13

[AE start date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 05 Apr 2021 14:53:43 |

US3302105

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:57:13

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Brittany Belcher (b) (4) | 05 Apr 2021 14:53:43 |
| | | |
| | | |

US3302105

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:57:13

If not Ongoing, end date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| | (b) (4) | |
| User entered empty. | Brittany Belcher (b) (4) | 05 Apr 2021 14:53:43 |
| | | |
| | | |

US3302105

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:57:13

End time (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| | (b) (4) | |
| User entered empty. | Brittany Belcher (b) (4) | 05 Apr 2021 14:53:43 |
| | | |
| | | |

US3302105

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:57:13

[AE End Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 05 Apr 2021 14:53:43 |

US3302105

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:57:13

[Severity](#)

| Audit | User | Time (GMT) |
|--|-------------------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| User entered 'Grade 2/Moderate (Grade 2/Moderate)' | (b) (4) Brittany Belcher (b) (4) | 05 Apr 2021 14:53:43 |
| | | |
| | | |

US3302105

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:57:13

[Is the adverse event serious?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| | (b) (4) | |
| User entered 'No (N)' | Brittany Belcher (b) (4) | 05 Apr 2021 14:53:43 |
| | | |
| | | |

US3302105

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:57:13

Death

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| | (b) (4) | |
| User entered '0' | Brittany Belcher (b) (4) | 05 Apr 2021 14:53:43 |
| | | |
| | | |

US3302105

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:57:13

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| | (b) (4) | |
| User entered '0' | Brittany Belcher (b) (4) | 05 Apr 2021 14:53:43 |
| | | |
| | | |

US3302105

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:57:13

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| | (b) (4) | |
| User entered '0' | Brittany Belcher (b) (4) | 05 Apr 2021 14:53:43 |
| | | |
| | | |

US3302105

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:57:13

Hospital Admission Date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| | (b) (4) | |
| User entered empty. | Brittany Belcher (b) (4) | 05 Apr 2021 14:53:43 |
| | | |
| | | |

US3302105

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:57:13

Hospital Discharge Date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| | (b) (4) | |
| User entered empty. | Brittany Belcher (b) (4) | 05 Apr 2021 14:53:43 |
| | | |
| | | |

US3302105

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:57:13

[Admitted to ICU?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| | (b) (4) | |
| User entered empty. | Brittany Belcher (b) (4) | 05 Apr 2021 14:53:43 |
| | | |
| | | |

US3302105

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:57:13

[Number of Days in ICU](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| | (b) (4) | |
| User entered empty. | Brittany Belcher (b) (4) | 05 Apr 2021 14:53:43 |
| | | |
| | | |

US3302105

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:57:13

Persistent or significant disability or incapacity

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| | (b) (4) | |
| User entered '0' | Brittany Belcher (b) (4) | 05 Apr 2021 14:53:43 |
| | | |
| | | |

US3302105

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:57:13

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| | (b) (4) | |
| User entered '0' | Brittany Belcher (b) (4) | 05 Apr 2021 14:53:43 |
| | | |
| | | |

US3302105

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:57:13

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| | (b) (4) | |
| User entered '0' | Brittany Belcher (b) (4) | 05 Apr 2021 14:53:43 |
| | | |
| | | |

US3302105

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:57:13

[Relationship to investigational product](#)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| | (b) (4) | |
| User entered 'Not Related (NOT RELATED)' | Brittany Belcher (b) (4) | 05 Apr 2021 14:53:43 |
| | | |
| | | |

US3302105

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:57:13

[Relationship to Study Procedure](#)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| | (b) (4) | |
| User entered 'Not Related (NOT RELATED)' | Brittany Belcher (b) (4) | 05 Apr 2021 14:53:43 |
| | | |
| | | |

US3302105

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:57:13

[Action taken with investigational product](#)

| Audit | User | Time (GMT) |
|--|-------------------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| User entered 'Not Applicable (NOT APPLICABLE)' | (b) (4) Brittany Belcher (b) (4) | 05 Apr 2021 14:53:43 |
| | | |
| | | |

US3302105

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:57:13

None

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| | (b) (4) | |
| User entered '0' | Brittany Belcher (b) (4) | 05 Apr 2021 14:53:43 |
| | | |
| | | |

US3302105

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:57:13

[Concomitant Medication](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| | (b) (4) | |
| User entered 'I' | Brittany Belcher (b) (4) | 05 Apr 2021 14:53:43 |
| | | |
| | | |

US3302105

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:57:13

[Concomitant Procedure](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| | (b) (4) | |
| User entered '0' | Brittany Belcher (b) (4) | 05 Apr 2021 14:53:43 |
| | | |
| | | |

US3302105

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:57:13

[Outcome](#)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| | (b) (4) | |
| User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' | Brittany Belcher (b) (4) | 05 Apr 2021 14:53:43 |
| | | |
| | | |

US3302105

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:57:13

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| | (b) (4) | |
| User entered empty. | Brittany Belcher (b) (4) | 05 Apr 2021 14:53:43 |
| | | |
| | | |

US3302105

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:57:13

[Narrative](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| | (b) (4) | |
| User entered empty. | Brittany Belcher (b) (4) | 05 Apr 2021 14:53:43 |
| | | |
| | | |

US3302105

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:57:13

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '0' | System | 05 Apr 2021 14:53:43 |

US3302105

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:57:13

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 05 Apr 2021 14:53:43 |

US3302105

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:57:13

[Adverse event](#)

| Audit | User | Time (GMT) |
|---|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| | (b) (4) | |
| User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Hyperglycaemic conditions NEC, PT: Hyperglycaemia, LLT: Hyperglycemia - version MedDRA\\23.0. | Coder Import (b) (4) | 05 Apr 2021 14:57:29 |
| | (b) (4) | |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 05 Apr 2021 14:57:29 |
| | (b) (4) | |
| Data point term sent to Coder | System | 05 Apr 2021 14:55:57 |
| User entered 'Hyperglycemia' | Brittany Belcher (b) (4) | 05 Apr 2021 14:55:32 |
| | | |
| | | |

US3302105

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:57:13

[Was this a medically-attended AE?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Brittany Belcher (b) (4) | 05 Apr 2021 14:55:32 |
| | | |
| | | |

US3302105

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:57:13

[Was this a Solicited Adverse Reaction?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| | (b) (4) | |
| User entered 'No (N)' | Brittany Belcher (b) (4) | 05 Apr 2021 14:55:32 |
| | | |
| | | |

US3302105

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:57:13

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| | (b) (4) | |
| User entered 'No (N)' | Brittany Belcher (b) (4) | 05 Apr 2021 14:55:32 |
| | | |
| | | |

US3302105

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:57:13

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| | (b) (4) | |
| User entered '20 Feb 2021' | Brittany Belcher (b) (4) | 05 Apr 2021 14:55:32 |
| | | |
| | | |

US3302105

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:57:13

[Start time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| | (b) (4) | |
| User entered empty. | Brittany Belcher (b) (4) | 05 Apr 2021 14:55:32 |
| | | |
| | | |

US3302105

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:57:13

[AE start date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 05 Apr 2021 14:55:32 |

US3302105

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:57:13

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Brittany Belcher (b) (4) | 05 Apr 2021 14:55:32 |
| | | |
| | | |

US3302105

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:57:13

If not Ongoing, end date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| | (b) (4) | |
| User entered empty. | Brittany Belcher (b) (4) | 05 Apr 2021 14:55:32 |
| | | |
| | | |

US3302105

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:57:13

End time (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| | (b) (4) | |
| User entered empty. | Brittany Belcher (b) (4) | 05 Apr 2021 14:55:32 |
| | | |
| | | |

US3302105

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:57:13

[AE End Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 05 Apr 2021 14:55:32 |

US3302105

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:57:13

[Severity](#)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| | (b) (4) | |
| User entered 'Grade 2/Moderate (Grade 2/Moderate)' | Brittany Belcher (b) (4) | 05 Apr 2021 14:55:32 |
| | | |
| | | |

US3302105

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:57:13

[Is the adverse event serious?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| | (b) (4) | |
| User entered 'No (N)' | Brittany Belcher (b) (4) | 05 Apr 2021 14:55:32 |
| | | |
| | | |

US3302105

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:57:13

Death

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| | (b) (4) | |
| User entered '0' | Brittany Belcher (b) (4) | 05 Apr 2021 14:55:32 |
| | | |
| | | |

US3302105

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:57:13

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| | (b) (4) | |
| User entered '0' | Brittany Belcher (b) (4) | 05 Apr 2021 14:55:32 |
| | | |
| | | |

US3302105

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:57:13

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| | (b) (4) | |
| User entered '0' | Brittany Belcher (b) (4) | 05 Apr 2021 14:55:32 |
| | | |
| | | |

US3302105

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:57:13

Hospital Admission Date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| | (b) (4) | |
| User entered empty. | Brittany Belcher (b) (4) | 05 Apr 2021 14:55:32 |
| | | |
| | | |

US3302105

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:57:13

Hospital Discharge Date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| | (b) (4) | |
| User entered empty. | Brittany Belcher (b) (4) | 05 Apr 2021 14:55:32 |
| | | |
| | | |

US3302105

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:57:13

[Admitted to ICU?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| | (b) (4) | |
| User entered empty. | Brittany Belcher (b) (4) | 05 Apr 2021 14:55:32 |
| | | |
| | | |

US3302105

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:57:13

[Number of Days in ICU](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| | (b) (4) | |
| User entered empty. | Brittany Belcher (b) (4) | 05 Apr 2021 14:55:32 |
| | | |
| | | |

US3302105

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:57:13

Persistent or significant disability or incapacity

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| | (b) (4) | |
| User entered '0' | Brittany Belcher (b) (4) | 05 Apr 2021 14:55:32 |
| | | |
| | | |

US3302105

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:57:13

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| | (b) (4) | |
| User entered '0' | Brittany Belcher (b) (4) | 05 Apr 2021 14:55:32 |
| | | |
| | | |

US3302105

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:57:13

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| | (b) (4) | |
| User entered '0' | Brittany Belcher (b) (4) | 05 Apr 2021 14:55:32 |
| | | |
| | | |

US3302105

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:57:13

[Relationship to investigational product](#)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| | (b) (4) | |
| User entered 'Not Related (NOT RELATED)' | Brittany Belcher (b) (4) | 05 Apr 2021 14:55:32 |
| | | |
| | | |

US3302105

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:57:13

[Relationship to Study Procedure](#)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| | (b) (4) | |
| User entered 'Not Related (NOT RELATED)' | Brittany Belcher (b) (4) | 05 Apr 2021 14:55:32 |
| | | |
| | | |

US3302105

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:57:13

[Action taken with investigational product](#)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| | (b) (4) | |
| User entered 'Not Applicable (NOT APPLICABLE)' | Brittany Belcher (b) (4) | 05 Apr 2021 14:55:32 |
| | | |
| | | |

US3302105

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:57:13

None

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| | (b) (4) | |
| User entered 'I' | Brittany Belcher (b) (4) | 05 Apr 2021 14:55:32 |
| | | |
| | | |

US3302105

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:57:13

[Concomitant Medication](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| | (b) (4) | |
| User entered '0' | Brittany Belcher (b) (4) | 05 Apr 2021 14:55:32 |
| | | |
| | | |

US3302105

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:57:13

[Concomitant Procedure](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| | (b) (4) | |
| User entered '0' | Brittany Belcher (b) (4) | 05 Apr 2021 14:55:32 |
| | | |
| | | |

US3302105

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:57:13

[Outcome](#)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| | (b) (4) | |
| User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' | Brittany Belcher (b) (4) | 05 Apr 2021 14:55:32 |
| | | |
| | | |

US3302105

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:57:13

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| | (b) (4) | |
| User entered empty. | Brittany Belcher (b) (4) | 05 Apr 2021 14:55:32 |
| | | |
| | | |

US3302105

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:57:13

[Narrative](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| | (b) (4) | |
| User entered empty. | Brittany Belcher (b) (4) | 05 Apr 2021 14:55:32 |
| | | |
| | | |

US3302105

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:57:13

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '0' | System | 05 Apr 2021 14:55:32 |

US3302105

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:57:13

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 05 Apr 2021 14:55:32 |

US3302105

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:57:13

[Adverse event](#)

| Audit | User | Time (GMT) |
|---|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| | (b) (4) | |
| User coded data point as SOC: Cardiac disorders, HLT: Cardiac valve disorders, HLT: Mitral valvular disorders, PT: Mitral valve incompetence, LLT: Mitral regurgitation - version MedDRA\\23.0. | Coder Import (b) (4) | 05 Apr 2021 15:07:43 |
| | (b) (4) | |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0. | Coder Import (b) (4) | 05 Apr 2021 15:07:43 |
| | (b) (4) | |
| Data point term sent to Coder | System | 05 Apr 2021 14:57:08 |
| User entered 'Mild Mitral Valve Regurgitation' | Brittany Belcher (b) (4) | 05 Apr 2021 14:56:47 |
| | | |
| | | |

US3302105

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:57:13

[Was this a medically-attended AE?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Brittany Belcher (b) (4) | 05 Apr 2021 14:56:47 |
| | | |
| | | |

US3302105

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:57:13

[Was this a Solicited Adverse Reaction?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| | (b) (4) | |
| User entered 'No (N)' | Brittany Belcher (b) (4) | 05 Apr 2021 14:56:47 |
| | | |
| | | |

US3302105

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:57:13

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| | (b) (4) | |
| User entered 'No (N)' | Brittany Belcher (b) (4) | 05 Apr 2021 14:56:47 |
| | | |
| | | |

US3302105

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:57:13

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| | (b) (4) | |
| User entered '20 Feb 2021' | Brittany Belcher (b) (4) | 05 Apr 2021 14:56:47 |
| | | |
| | | |

US3302105

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:57:13

[Start time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| | (b) (4) | |
| User entered empty. | Brittany Belcher (b) (4) | 05 Apr 2021 14:56:47 |
| | | |
| | | |

US3302105

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:57:13

[AE start date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 05 Apr 2021 14:56:47 |

US3302105

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:57:13

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Brittany Belcher (b) (4) | 05 Apr 2021 14:56:47 |
| | | |
| | | |

US3302105

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:57:13

If not Ongoing, end date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| | (b) (4) | |
| User entered empty. | Brittany Belcher (b) (4) | 05 Apr 2021 14:56:47 |
| | | |
| | | |

US3302105

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:57:13

[End time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| | (b) (4) | |
| User entered empty. | Brittany Belcher (b) (4) | 05 Apr 2021 14:56:47 |
| | | |
| | | |

US3302105

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:57:13

[AE End Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 05 Apr 2021 14:56:47 |

US3302105

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:57:13

[Severity](#)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| | (b) (4) | |
| User entered 'Grade 2/Moderate (Grade 2/Moderate)' | Brittany Belcher (b) (4) | 05 Apr 2021 14:56:47 |
| | | |
| | | |

US3302105

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:57:13

[Is the adverse event serious?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| | (b) (4) | |
| User entered 'No (N)' | Brittany Belcher (b) (4) | 05 Apr 2021 14:56:47 |
| | | |
| | | |

US3302105

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:57:13

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| | (b) (4) | |
| User entered '0' | Brittany Belcher (b) (4) | 05 Apr 2021 14:56:47 |
| | | |
| | | |

US3302105

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:57:13

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| | (b) (4) | |
| User entered '0' | Brittany Belcher (b) (4) | 05 Apr 2021 14:56:47 |
| | | |
| | | |

US3302105

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:57:13

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| | (b) (4) | |
| User entered '0' | Brittany Belcher (b) (4) | 05 Apr 2021 14:56:47 |
| | | |
| | | |

US3302105

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:57:13

Hospital Admission Date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| | (b) (4) | |
| User entered empty. | Brittany Belcher (b) (4) | 05 Apr 2021 14:56:47 |
| | | |
| | | |

US3302105

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:57:13

Hospital Discharge Date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| | (b) (4) | |
| User entered empty. | Brittany Belcher (b) (4) | 05 Apr 2021 14:56:47 |
| | | |
| | | |

US3302105

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:57:13

[Admitted to ICU?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| | (b) (4) | |
| User entered empty. | Brittany Belcher (b) (4) | 05 Apr 2021 14:56:47 |
| | | |
| | | |

US3302105

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:57:13

[Number of Days in ICU](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| | (b) (4) | |
| User entered empty. | Brittany Belcher (b) (4) | 05 Apr 2021 14:56:47 |
| | | |
| | | |

US3302105

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:57:13

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| | (b) (4) | |
| User entered '0' | Brittany Belcher (b) (4) | 05 Apr 2021 14:56:47 |
| | | |
| | | |

US3302105

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:57:13

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| | (b) (4) | |
| User entered '0' | Brittany Belcher (b) (4) | 05 Apr 2021 14:56:47 |
| | | |
| | | |

US3302105

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:57:13

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| | (b) (4) | |
| User entered '0' | Brittany Belcher (b) (4) | 05 Apr 2021 14:56:47 |
| | | |
| | | |

US3302105

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:57:13

[Relationship to investigational product](#)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| | (b) (4) | |
| User entered 'Not Related (NOT RELATED)' | Brittany Belcher (b) (4) | 05 Apr 2021 14:56:47 |
| | | |
| | | |

US3302105

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:57:13

[Relationship to Study Procedure](#)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| | (b) (4) | |
| User entered 'Not Related (NOT RELATED)' | Brittany Belcher (b) (4) | 05 Apr 2021 14:56:47 |
| | | |
| | | |

US3302105

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:57:13

[Action taken with investigational product](#)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| | (b) (4) | |
| User entered 'Not Applicable (NOT APPLICABLE)' | Brittany Belcher (b) (4) | 05 Apr 2021 14:56:47 |
| | | |
| | | |

US3302105

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:57:13

None

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| | (b) (4) | |
| User entered 'I' | Brittany Belcher (b) (4) | 05 Apr 2021 14:56:47 |
| | | |
| | | |

US3302105

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:57:13

[Concomitant Medication](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| | (b) (4) | |
| User entered '0' | Brittany Belcher (b) (4) | 05 Apr 2021 14:56:47 |
| | | |
| | | |

US3302105

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:57:13

[Concomitant Procedure](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| | (b) (4) | |
| User entered '0' | Brittany Belcher (b) (4) | 05 Apr 2021 14:56:47 |
| | | |
| | | |

US3302105

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:57:13

[Outcome](#)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| | (b) (4) | |
| User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' | Brittany Belcher (b) (4) | 05 Apr 2021 14:56:47 |
| | | |
| | | |

US3302105

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:57:13

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| | (b) (4) | |
| User entered empty. | Brittany Belcher (b) (4) | 05 Apr 2021 14:56:47 |
| | | |
| | | |

US3302105

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:57:13

[Narrative](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| | (b) (4) | |
| User entered empty. | Brittany Belcher (b) (4) | 05 Apr 2021 14:56:47 |
| | | |
| | | |

US3302105

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:57:13

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '0' | System | 05 Apr 2021 14:56:47 |

US3302105

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:57:13

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 05 Apr 2021 14:56:47 |

US3302105

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:57:13

[AEID](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 09:48:42 |
| | | |

US3302105

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:57:13

[Adverse event](#)

| Audit | User | Time (GMT) |
|---|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 09:48:42 |
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Pain and discomfort NEC, PT: Chest discomfort, LLT: Chest pressure - version MedDRA\\23.0. | Coder Import (b) (4) | 13 Apr 2021 12:53:56 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 13 Apr 2021 12:53:56 |
| Data point term sent to Coder | System | 13 Apr 2021 12:53:30 |
| User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Pain and discomfort NEC, PT: Chest discomfort, LLT: Chest pressure - version MedDRA\\23.0. | Coder Import (b) (4) | 13 Apr 2021 12:53:07 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 13 Apr 2021 12:53:07 |
| Query 'CDM Coding, please split the term (CHEST PRESSURE WITH DYSPNE) into separate records, as 'CHEST PRESSURE' and 'DYSPNE' reporting each term separately with all relevant information e.g. start and stop dates etc. ' canceled (Site from System). | Coder Import (b) (4) | 13 Apr 2021 12:52:59 |
| Data point term sent to Coder | System | 13 Apr 2021 12:52:29 |
| User entered 'CHEST PRESSURE' reason for change: Data Entry Error | Brittany Belcher (b) (4) | 13 Apr 2021 12:52:05 |
| User opened query 'CDM Coding, please split the term (CHEST PRESSURE WITH DYSPNE) into separate records, as 'CHEST PRESSURE' and 'DYSPNE' reporting each term separately with all relevant information e.g. start and stop dates etc. ' (Site from System). | Coder Import (b) (4) | 07 Apr 2021 06:40:24 |
| Data point term sent to Coder | System | 05 Apr 2021 14:58:09 |
| User entered 'Chest Pressure with Dyspnea' | Brittany Belcher (b) (4) | 05 Apr 2021 14:57:26 |

US3302105

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:57:13

[Was this a medically-attended AE?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 09:48:42 |
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| User entered 'Yes (Y)' | (b) (4) Brittany Belcher (b) (4) | 05 Apr 2021 14:57:26 |

US3302105

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:57:13

[Was this a Solicited Adverse Reaction?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 09:48:42 |
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| User entered 'No (N)' | (b) (4) Brittany Belcher (b) (4) | 05 Apr 2021 14:57:26 |

US3302105

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:57:13

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 09:48:42 |
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| User entered 'No (N)' | (b) (4) Brittany Belcher (b) (4) | 05 Apr 2021 14:57:26 |

US3302105

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:57:13

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 09:48:42 |
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| User entered '19 Feb 2021' | (b) (4) | 05 Apr 2021 14:57:26 |

US3302105

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:57:13

[Start time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 09:48:42 |
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| User entered empty. | (b) (4) Brittany Belcher (b) (4) | 05 Apr 2021 14:57:26 |

US3302105

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:57:13

[AE start date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 09:48:42 |
| User entered empty. | System | 05 Apr 2021 14:57:26 |

US3302105

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:57:13

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 09:48:42 |
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| User entered 'No (N)' | (b) (4) Brittany Belcher (b) (4) | 05 Apr 2021 14:57:26 |

US3302105

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:57:13

If not Ongoing, end date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 09:48:42 |
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| User entered '19 Feb 2021' | (b) (4) | 05 Apr 2021 14:57:26 |

US3302105

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:57:13

[End time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 09:48:42 |
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| User entered empty. | (b) (4) Brittany Belcher (b) (4) | 05 Apr 2021 14:57:26 |

US3302105

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:57:13

[AE End Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 09:48:42 |
| User entered empty. | System | 05 Apr 2021 14:57:26 |

US3302105

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:57:13

[Severity](#)

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 09:48:42 |
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| User entered 'Grade 2/Moderate (Grade 2/Moderate)' | (b) (4) Brittany Belcher (b) (4) | 05 Apr 2021 14:57:26 |

US3302105

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:57:13

[Is the adverse event serious?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 09:48:42 |
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| User entered 'No (N)' | (b) (4) | 05 Apr 2021 14:57:26 |

US3302105

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:57:13

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 09:48:42 |
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| User entered '0' | (b) (4) Brittany Belcher (b) (4) | 05 Apr 2021 14:57:26 |

US3302105

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:57:13

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 09:48:42 |
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| User entered '0' | (b) (4) Brittany Belcher (b) (4) | 05 Apr 2021 14:57:26 |

US3302105

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:57:13

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 09:48:42 |
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| User entered '0' | (b) (4) Brittany Belcher (b) (4) | 05 Apr 2021 14:57:26 |

US3302105

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:57:13

Hospital Admission Date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 09:48:42 |
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| User entered empty. | (b) (4) | 05 Apr 2021 14:57:26 |

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:57:13

Hospital Discharge Date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 09:48:42 |
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| User entered empty. | (b) (4) | 05 Apr 2021 14:57:26 |

US3302105

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:57:13

[Admitted to ICU?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 09:48:42 |
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| User entered empty. | (b) (4) Brittany Belcher (b) (4) | 05 Apr 2021 14:57:26 |

US3302105

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:57:13

[Number of Days in ICU](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 09:48:42 |
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| User entered empty. | (b) (4) | 05 Apr 2021 14:57:26 |

US3302105

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:57:13

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 09:48:42 |
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| User entered '0' | (b) (4) Brittany Belcher (b) (4) | 05 Apr 2021 14:57:26 |

US3302105

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:57:13

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 09:48:42 |
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| User entered '0' | (b) (4) Brittany Belcher (b) (4) | 05 Apr 2021 14:57:26 |

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:57:13

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 09:48:42 |
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| User entered '0' | (b) (4) Brittany Belcher (b) (4) | 05 Apr 2021 14:57:26 |

US3302105

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:57:13

[Relationship to investigational product](#)

| Audit | User | Time (GMT) |
|--|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 09:48:42 |
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| User entered 'Not Related (NOT RELATED)' | (b) (4) Brittany Belcher (b) (4) | 05 Apr 2021 14:57:26 |

US3302105

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:57:13

[Relationship to Study Procedure](#)

| Audit | User | Time (GMT) |
|--|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 09:48:42 |
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| User entered 'Not Related (NOT RELATED)' | (b) (4) Brittany Belcher (b) (4) | 05 Apr 2021 14:57:26 |

US3302105

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:57:13

[Action taken with investigational product](#)

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 09:48:42 |
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| User entered 'Not Applicable (NOT APPLICABLE)' | (b) (4) Brittany Belcher (b) (4) | 05 Apr 2021 14:57:26 |

US3302105

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:57:13

[None](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 09:48:42 |
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| User entered 'I' | (b) (4) Brittany Belcher (b) (4) | 05 Apr 2021 14:57:26 |

US3302105

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:57:13

[Concomitant Medication](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 09:48:42 |
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| User entered '0' | (b) (4) Brittany Belcher (b) (4) | 05 Apr 2021 14:57:26 |

US3302105

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:57:13

[Concomitant Procedure](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 09:48:42 |
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| User entered '0' | (b) (4) Brittany Belcher (b) (4) | 05 Apr 2021 14:57:26 |

US3302105

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:57:13

[Outcome](#)

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 09:48:42 |
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' | (b) (4) Brittany Belcher (b) (4) | 05 Apr 2021 14:57:26 |

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:57:13

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 09:48:42 |
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| User entered empty. | (b) (4) Brittany Belcher (b) (4) | 05 Apr 2021 14:57:26 |

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:57:13

[Narrative](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 09:48:42 |
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| User entered empty. | (b) (4) Brittany Belcher (b) (4) | 05 Apr 2021 14:57:26 |

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:57:13

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 09:48:42 |
| User entered '0' | System | 05 Apr 2021 14:57:26 |

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:57:13

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 09:48:42 |
| User entered 'I' | System | 05 Apr 2021 14:57:26 |

US3302105

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:57:13

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 09:48:42 |
| | | |

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:57:13

[Adverse event](#)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| User coded data point as SOC: Cardiac disorders, HLGT: Coronary artery disorders, HLT: Coronary artery disorders NEC, PT: Coronary artery disease, LLT: Coronary artery disease - version MedDRA\23.0. | Coder Import (b) (4) | 05 Apr 2021 15:22:17 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0. | Coder Import (b) (4) | 05 Apr 2021 15:22:17 |
| Data point term sent to Coder | System | 05 Apr 2021 15:00:12 |
| Coding entries removed. | Brittany Belcher (b) (4) | 05 Apr 2021 14:59:51 |
| User entered 'CORONARY ARTERY DISEASE (CAD; Non-Obstructive)' reason for change: Data Entry Error | Brittany Belcher (b) (4) | 05 Apr 2021 14:59:51 |
| User coded data point as SOC: Cardiac disorders, HLGT: Coronary artery disorders, HLT: Coronary artery disorders NEC, PT: Coronary artery disease, LLT: Coronary artery disease - version MedDRA\23.0. | Coder Import (b) (4) | 05 Apr 2021 14:59:18 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0. | Coder Import (b) (4) | 05 Apr 2021 14:59:18 |
| Data point term sent to Coder | System | 05 Apr 2021 14:58:09 |
| User entered 'Coronary Artery Disease (CAD)' | Brittany Belcher (b) (4) | 05 Apr 2021 14:58:04 |

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:57:13

[Was this a medically-attended AE?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Brittany Belcher (b) (4) | 05 Apr 2021 14:58:04 |
| | | |
| | | |

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:57:13

[Was this a Solicited Adverse Reaction?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| | (b) (4) | |
| User entered 'No (N)' | Brittany Belcher (b) (4) | 05 Apr 2021 14:58:04 |
| | | |
| | | |

US3302105

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:57:13

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| | (b) (4) | |
| User entered 'No (N)' | Brittany Belcher (b) (4) | 05 Apr 2021 14:58:04 |
| | | |
| | | |

US3302105

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:57:13

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| | (b) (4) | |
| User entered '19 Feb 2021' | Brittany Belcher (b) (4) | 05 Apr 2021 14:58:04 |
| | | |
| | | |

US3302105

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:57:13

[Start time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| | (b) (4) | |
| User entered empty. | Brittany Belcher (b) (4) | 05 Apr 2021 14:58:04 |
| | | |
| | | |

US3302105

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:57:13

[AE start date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 05 Apr 2021 14:58:04 |

US3302105

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:57:13

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Brittany Belcher (b) (4) | 05 Apr 2021 14:58:04 |
| | | |
| | | |

US3302105

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:57:13

If not Ongoing, end date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| | (b) (4) | |
| User entered empty. | Brittany Belcher (b) (4) | 05 Apr 2021 14:58:04 |
| | | |
| | | |

US3302105

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:57:13

End time (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| | (b) (4) | |
| User entered empty. | Brittany Belcher (b) (4) | 05 Apr 2021 14:58:04 |
| | | |
| | | |

US3302105

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:57:13

[AE End Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 05 Apr 2021 14:58:04 |

US3302105

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:57:13

[Severity](#)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| | (b) (4) | |
| User entered 'Grade 2/Moderate (Grade 2/Moderate)' | Brittany Belcher (b) (4) | 05 Apr 2021 14:58:04 |
| | | |
| | | |

US3302105

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:57:13

[Is the adverse event serious?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| | (b) (4) | |
| User entered 'No (N)' | Brittany Belcher (b) (4) | 05 Apr 2021 14:58:04 |
| | | |
| | | |

US3302105

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:57:13

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| | (b) (4) | |
| User entered '0' | Brittany Belcher (b) (4) | 05 Apr 2021 14:58:04 |
| | | |
| | | |

US3302105

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:57:13

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| | (b) (4) | |
| User entered '0' | Brittany Belcher (b) (4) | 05 Apr 2021 14:58:04 |
| | | |
| | | |

US3302105

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:57:13

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| | (b) (4) | |
| User entered '0' | Brittany Belcher (b) (4) | 05 Apr 2021 14:58:04 |
| | | |
| | | |

US3302105

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:57:13

Hospital Admission Date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| | (b) (4) | |
| User entered empty. | Brittany Belcher (b) (4) | 05 Apr 2021 14:58:04 |
| | | |
| | | |

US3302105

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:57:13

Hospital Discharge Date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| | (b) (4) | |
| User entered empty. | Brittany Belcher (b) (4) | 05 Apr 2021 14:58:04 |
| | | |
| | | |

US3302105

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:57:13

[Admitted to ICU?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| | (b) (4) | |
| User entered empty. | Brittany Belcher (b) (4) | 05 Apr 2021 14:58:04 |
| | | |
| | | |

US3302105

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:57:13

[Number of Days in ICU](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| | (b) (4) | |
| User entered empty. | Brittany Belcher (b) (4) | 05 Apr 2021 14:58:04 |
| | | |
| | | |

US3302105

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:57:13

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| | (b) (4) | |
| User entered '0' | Brittany Belcher (b) (4) | 05 Apr 2021 14:58:04 |
| | | |
| | | |

US3302105

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:57:13

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| | (b) (4) | |
| User entered '0' | Brittany Belcher (b) (4) | 05 Apr 2021 14:58:04 |
| | | |
| | | |

US3302105

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:57:13

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| | (b) (4) | |
| User entered '0' | Brittany Belcher (b) (4) | 05 Apr 2021 14:58:04 |
| | | |
| | | |

US3302105

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:57:13

[Relationship to investigational product](#)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| | (b) (4) | |
| User entered 'Not Related (NOT RELATED)' | Brittany Belcher (b) (4) | 05 Apr 2021 14:58:04 |
| | | |
| | | |

US3302105

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:57:13

[Relationship to Study Procedure](#)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| | (b) (4) | |
| User entered 'Not Related (NOT RELATED)' | Brittany Belcher (b) (4) | 05 Apr 2021 14:58:04 |
| | | |
| | | |

US3302105

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:57:13

[Action taken with investigational product](#)

| Audit | User | Time (GMT) |
|--|-------------------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| User entered 'Not Applicable (NOT APPLICABLE)' | (b) (4) Brittany Belcher (b) (4) | 05 Apr 2021 14:58:04 |
| | | |
| | | |

US3302105

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:57:13

None

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| | (b) (4) | |
| User entered '0' | Brittany Belcher (b) (4) | 05 Apr 2021 14:58:04 |
| | | |
| | | |

US3302105

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:57:13

[Concomitant Medication](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| | (b) (4) | |
| User entered 'I' | Brittany Belcher (b) (4) | 05 Apr 2021 14:58:04 |
| | | |
| | | |

US3302105

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:57:13

[Concomitant Procedure](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| | (b) (4) | |
| User entered '0' | Brittany Belcher (b) (4) | 05 Apr 2021 14:58:04 |
| | | |
| | | |

US3302105

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:57:13

[Outcome](#)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| | (b) (4) | |
| User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' | Brittany Belcher (b) (4) | 05 Apr 2021 14:58:04 |
| | | |
| | | |

US3302105

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:57:13

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| | (b) (4) | |
| User entered empty. | Brittany Belcher (b) (4) | 05 Apr 2021 14:58:04 |
| | | |
| | | |

US3302105

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:57:13

[Narrative](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| | (b) (4) | |
| User entered empty. | Brittany Belcher (b) (4) | 05 Apr 2021 14:58:04 |
| | | |
| | | |

US3302105

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:57:13

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '0' | System | 05 Apr 2021 14:58:04 |

US3302105

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:57:13

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 05 Apr 2021 14:58:04 |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 16:57:13

[Were any prior/concomitant medications and/or vaccinations taken?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 05:15:55 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:02:55 |
| User entered 'Yes (Y)' | (b) (4) Brittany Belcher (b) (4) | 07 Aug 2020 20:36:31 |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:57:13

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--|--|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:02:55 |
| User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: DIURETICS AND POTASSIUM-SPARING AGENTS IN COMBINATION, ATC: LOW-CEILING DIURETICS AND POTASSIUM-SPARING AGENTS, PRODUCT: HYDROCHLOROTHIAZIDE;TRIAMTERENE, PRODUCTSYNONYM: TRIAMTERENE HCTZ - version WHODrug-Global-B3\\202003. | (b) (4) Coder Import (b) (4) (b) (4) | 07 Aug 2020 20:38:12 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 07 Aug 2020 20:38:12 |
| Data point term sent to Coder | System | 07 Aug 2020 20:37:40 |
| User entered 'Triamterene HCTZ' | Brittany Belcher (b) (4) (b) (4) (b) (4) | 07 Aug 2020 20:37:37 |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:57:13

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:02:55 |
| | (b) (4) | |
| User entered 'No (N)' | Brittany Belcher (b) (4) | 07 Aug 2020 20:37:37 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:57:13

[Indication](#)

| Audit | User | Time (GMT) |
|-----------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:02:55 |
| | (b) (4) | |
| User entered 'hypertension' | Brittany Belcher (b) (4) | 07 Aug 2020 20:37:37 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:57:13

[Dose per administration](#)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:02:55 |
| User closed query 'Per DM CLR: Please review the recorded combination dose as this is not an available combination dosage for this medication. Please review and update combination dose if appropriate. Otherwise, clarify.' (Site from DM). | (b) (4) | |
| Query 'Per DM CLR: Please review the recorded combination dose as this is not an available combination dosage for this medication. Please review and update combination dose if appropriate. Otherwise, clarify.' answered with 'Data entered is correct.' (Site from DM). | (b) (4), (b) (6) | 12 Oct 2020 20:16:40 |
| User opened query 'Per DM CLR: Please review the recorded combination dose as this is not an available combination dosage for this medication. Please review and update combination dose if appropriate. Otherwise, clarify.' (Site from DM). | Brittany Belcher (b) (4) | 09 Oct 2020 12:39:31 |
| User entered '37.5/12.5' | (b) (4), (b) (6) | 21 Sep 2020 06:44:53 |
| | Brittany Belcher (b) (4) | 07 Aug 2020 20:37:37 |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:57:13

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:02:55 |
| | (b) (4) | |
| User entered 'mg (mg)' | Brittany Belcher (b) (4) | 07 Aug 2020 20:37:37 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:57:13

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:02:55 |
| | (b) (4) | |
| User entered empty. | Brittany Belcher (b) (4) | 07 Aug 2020 20:37:37 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:57:13

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:02:55 |
| | (b) (4) | |
| User entered 'once daily (QD)' | Brittany Belcher (b) (4) | 07 Aug 2020 20:37:37 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:57:13

If frequency is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:02:55 |
| | (b) (4) | |
| User entered empty. | Brittany Belcher (b) (4) | 07 Aug 2020 20:37:37 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:57:13

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:02:55 |
| | (b) (4) | |
| User entered 'Oral (ORAL)' | Brittany Belcher (b) (4) | 07 Aug 2020 20:37:37 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:57:13

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:02:55 |
| | (b) (4) | |
| User entered empty. | Brittany Belcher (b) (4) | 07 Aug 2020 20:37:37 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:57:13

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:02:55 |
| 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) (4), (b) (6) | 10 Aug 2020 09:38:14 |
| 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 'ongoing' (Site from System). | Brittany Belcher (b) (4) | 07 Aug 2020 20:39:10 |
| 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 | 07 Aug 2020 20:37:37 |
| User entered 'un UNK 2014' | Brittany Belcher (b) (4) | 07 Aug 2020 20:37:37 |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:57:13

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:02:55 |
| | (b) (4) | |
| User entered '0' | Brittany Belcher (b) (4) | 07 Aug 2020 20:37:37 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:57:13

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:02:55 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Brittany Belcher (b) (4) | 07 Aug 2020 20:37:37 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:57:13

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:02:55 |
| | (b) (4) | |
| User entered empty. | Brittany Belcher (b) (4) | 07 Aug 2020 20:37:37 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:57:13

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:02:55 |
| | (b) (4) | |
| User entered 'No (N)' | Brittany Belcher (b) (4) | 07 Aug 2020 20:37:37 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:57:13

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 07 Aug 2020 20:37:37 |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:57:13

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 07 Aug 2020 20:37:37 |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:57:13

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 07 Aug 2020 20:37:37 |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:57:13

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--|--|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:02:55 |
| User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003. | (b) (4) Coder Import (b) (4) | 07 Aug 2020 20:40:15 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 07 Aug 2020 20:40:15 |
| Data point term sent to Coder | System | 07 Aug 2020 20:38:44 |
| User entered 'tylenol' | Brittany Belcher (b) (4) (b) (4) (b) (4) | 07 Aug 2020 20:38:10 |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:57:13

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:02:55 |
| | (b) (4) | |
| User entered 'No (N)' | Brittany Belcher (b) (4) | 07 Aug 2020 20:38:10 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:57:13

[Indication](#)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:02:55 |
| Query 'Per DM CLR: Please review Indication and please update to specify the location (e.g. Knees, Elbows, Hips, etc.) and specify the type (e.g. Osteoarthritis, Rheumatoid, etc.) of Arthritis. Please update and reconcile with MH eCRF so there would be an appropriate match. Otherwise, clarify.' canceled (Site from DM). | (b) (4) (b) (4), (b) (6) | 30 Sep 2020 11:27:36 |
| User opened query 'Per DM CLR: Please review Indication and please update to specify the location (e.g. Knees, Elbows, Hips, etc.) and specify the type (e.g. Osteoarthritis, Rheumatoid, etc.) of Arthritis. Please update and reconcile with MH eCRF so there would be an appropriate match. Otherwise, clarify.' (Site from DM). | (b) (4), (b) (6) | 21 Sep 2020 06:45:14 |
| User entered 'arthritis' | Brittany Belcher (b) (4) | 07 Aug 2020 20:38:10 |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:57:13

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:02:55 |
| | (b) (4) | |
| User entered '325' | Brittany Belcher (b) (4) | 07 Aug 2020 20:38:10 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:57:13

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:02:55 |
| | (b) (4) | |
| User entered 'mg (mg)' | Brittany Belcher (b) (4) | 07 Aug 2020 20:38:10 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:57:13

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:02:55 |
| | (b) (4) | |
| User entered empty. | Brittany Belcher (b) (4) | 07 Aug 2020 20:38:10 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:57:13

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:02:55 |
| | (b) (4) | |
| User entered 'as needed (PRN)' | Brittany Belcher (b) (4) | 07 Aug 2020 20:38:10 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:57:13

If frequency is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:02:55 |
| | (b) (4) | |
| User entered empty. | Brittany Belcher (b) (4) | 07 Aug 2020 20:38:10 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:57:13

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:02:55 |
| | (b) (4) | |
| User entered 'Oral (ORAL)' | Brittany Belcher (b) (4) | 07 Aug 2020 20:38:10 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:57:13

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:02:55 |
| | (b) (4) | |
| User entered empty. | Brittany Belcher (b) (4) | 07 Aug 2020 20:38:10 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:57:13

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:02:55 |
| 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) (4), (b) (6) | 10 Aug 2020 09:38:23 |
| 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 'ongoing' (Site from System). | Brittany Belcher (b) (4) | 07 Aug 2020 20:39:05 |
| 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 | 07 Aug 2020 20:38:10 |
| User entered 'un UNK 1990' | Brittany Belcher (b) (4) | 07 Aug 2020 20:38:10 |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:57:13

Start date completely unknown

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:02:55 |
| | (b) (4) | |
| User entered '0' | Brittany Belcher (b) (4) | 07 Aug 2020 20:38:10 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:57:13

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:02:55 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Brittany Belcher (b) (4) | 07 Aug 2020 20:38:10 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:57:13

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:02:55 |
| | (b) (4) | |
| User entered empty. | Brittany Belcher (b) (4) | 07 Aug 2020 20:38:10 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:57:13

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:02:55 |
| | (b) (4) | |
| User entered 'No (N)' | Brittany Belcher (b) (4) | 07 Aug 2020 20:38:10 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:57:13

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 07 Aug 2020 20:38:10 |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:57:13

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 07 Aug 2020 20:38:10 |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:57:13

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 07 Aug 2020 20:38:10 |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:57:13

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--|--|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:02:55 |
| User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003. | (b) (4) Coder Import (b) (4) (b) (4) | 07 Aug 2020 20:40:15 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 07 Aug 2020 20:40:15 |
| Data point term sent to Coder | System | 07 Aug 2020 20:39:46 |
| User entered 'ibuprofen' | Brittany Belcher (b) (4) (b) (4) (b) (4) | 07 Aug 2020 20:38:52 |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:57:13

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:02:55 |
| | (b) (4) | |
| User entered 'No (N)' | Brittany Belcher (b) (4) | 07 Aug 2020 20:38:52 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:57:13

[Indication](#)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:02:55 |
| Query 'Per DM CLR: Please review Indication and please update to specify the location (e.g. Knees, Elbows, Hips, etc.) and specify the type (e.g. Osteoarthritis, Rheumatoid, etc.) of Arthritis. Please update and reconcile with MH eCRF so there would be an appropriate match. Otherwise, clarify.' canceled (Site from DM). | (b) (4) (b) (4), (b) (6) | 30 Sep 2020 11:27:49 |
| User opened query 'Per DM CLR: Please review Indication and please update to specify the location (e.g. Knees, Elbows, Hips, etc.) and specify the type (e.g. Osteoarthritis, Rheumatoid, etc.) of Arthritis. Please update and reconcile with MH eCRF so there would be an appropriate match. Otherwise, clarify.' (Site from DM). | (b) (4), (b) (6) | 21 Sep 2020 06:44:26 |
| User entered 'arthritis' | Brittany Belcher (b) (4) | 07 Aug 2020 20:38:52 |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:57:13

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:02:55 |
| | (b) (4) | |
| User entered '200' | Brittany Belcher (b) (4) | 07 Aug 2020 20:38:52 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:57:13

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:02:55 |
| | (b) (4) | |
| User entered 'mg (mg)' | Brittany Belcher (b) (4) | 07 Aug 2020 20:38:52 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:57:13

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:02:55 |
| | (b) (4) | |
| User entered empty. | Brittany Belcher (b) (4) | 07 Aug 2020 20:38:52 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:57:13

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:02:55 |
| | (b) (4) | |
| User entered 'as needed (PRN)' | Brittany Belcher (b) (4) | 07 Aug 2020 20:38:52 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:57:13

If frequency is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:02:55 |
| | (b) (4) | |
| User entered empty. | Brittany Belcher (b) (4) | 07 Aug 2020 20:38:52 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:57:13

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:02:55 |
| | (b) (4) | |
| User entered 'Oral (ORAL)' | Brittany Belcher (b) (4) | 07 Aug 2020 20:38:52 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:57:13

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:02:55 |
| | (b) (4) | |
| User entered empty. | Brittany Belcher (b) (4) | 07 Aug 2020 20:38:52 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:57:13

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:02:55 |
| 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) (4), (b) (6) | 10 Aug 2020 09:38:33 |
| 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 'ongoing' (Site from System). | Brittany Belcher (b) (4) | 07 Aug 2020 20:38:56 |
| 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 | 07 Aug 2020 20:38:52 |
| User entered 'un UNK 1990' | Brittany Belcher (b) (4) | 07 Aug 2020 20:38:52 |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:57:13

Start date completely unknown

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:02:55 |
| | (b) (4) | |
| User entered '0' | Brittany Belcher (b) (4) | 07 Aug 2020 20:38:52 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:57:13

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:02:55 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Brittany Belcher (b) (4) | 07 Aug 2020 20:38:52 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:57:13

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:02:55 |
| | (b) (4) | |
| User entered empty. | Brittany Belcher (b) (4) | 07 Aug 2020 20:38:52 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:57:13

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:02:55 |
| | (b) (4) | |
| User entered 'No (N)' | Brittany Belcher (b) (4) | 07 Aug 2020 20:38:52 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:57:13

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 07 Aug 2020 20:38:52 |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:57:13

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 07 Aug 2020 20:38:52 |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:57:13

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 07 Aug 2020 20:38:52 |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:57:13

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:07:34 |
| | | |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:02:55 |
| | (b) (4) | |
| User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: COMBINATIONS OF PENICILLINS, INCL. BETA-LACTAMASE INHIBITORS, PRODUCT: AMOXICILLIN;CLAVULANIC ACID, PRODUCTSYNONYM: AUGMENTIN [AMOXICILLIN;CLAVULANIC ACID] - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 16 Feb 2021 17:35:07 |
| | (b) (4) | |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 16 Feb 2021 17:35:07 |
| | (b) (4) | |
| Data point term sent to Coder | System | 16 Feb 2021 16:38:23 |
| User entered 'Augmentin' | Brittany Belcher (b) (4) | 16 Feb 2021 16:37:58 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:57:13

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:07:34 |
| | | |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:02:55 |
| | (b) (4) | |
| User entered 'No (N)' | Brittany Belcher (b) (4) | 16 Feb 2021 16:37:58 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:57:13

[Indication](#)

| Audit | User | Time (GMT) |
|------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:07:34 |
| | | |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:02:55 |
| | (b) (4) | |
| User entered 'Tooth Abscess' | Brittany Belcher (b) (4) | 16 Feb 2021 16:37:58 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:57:13

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:07:34 |
| | | |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:02:55 |
| | (b) (4) | |
| User entered '875/125' | Brittany Belcher (b) (4) | 16 Feb 2021 16:37:58 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:57:13

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:07:34 |
| | | |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:02:55 |
| | (b) (4) | |
| User entered 'mg (mg)' | Brittany Belcher (b) (4) | 16 Feb 2021 16:37:58 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:57:13

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:07:34 |
| | | |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:02:55 |
| | (b) (4) | |
| User entered empty. | Brittany Belcher (b) (4) | 16 Feb 2021 16:37:58 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:57:13

[Frequency](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:07:34 |
| | | |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:02:55 |
| | (b) (4) | |
| User entered 'twice daily (BID)' | Brittany Belcher (b) (4) | 16 Feb 2021 16:37:58 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:57:13

If frequency is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:07:34 |
| | | |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:02:55 |
| | (b) (4) | |
| User entered empty. | Brittany Belcher (b) (4) | 16 Feb 2021 16:37:58 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:57:13

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:07:34 |
| | | |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:02:55 |
| | (b) (4) | |
| User entered 'Oral (ORAL)' | Brittany Belcher (b) (4) | 16 Feb 2021 16:37:58 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:57:13

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:07:34 |
| | | |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:02:55 |
| | (b) (4) | |
| User entered empty. | Brittany Belcher (b) (4) | 16 Feb 2021 16:37:58 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:57:13

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:07:34 |
| | | |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:02:55 |
| | (b) (4) | |
| User entered '18 Jan 2021' | Brittany Belcher (b) (4) | 16 Feb 2021 16:37:58 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:57:13

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:07:34 |
| | | |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:02:55 |
| | (b) (4) | |
| User entered '0' | Brittany Belcher (b) (4) | 16 Feb 2021 16:37:58 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:57:13

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:07:34 |
| | | |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:02:55 |
| | (b) (4) | |
| User entered 'No (N)' | Brittany Belcher (b) (4) | 16 Feb 2021 16:37:58 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:57:13

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:07:34 |
| | | |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:02:55 |
| | (b) (4) | |
| User entered '19 Jan 2021' | Brittany Belcher (b) (4) | 16 Feb 2021 16:37:58 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:57:13

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:07:34 |
| | | |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:02:55 |
| | (b) (4) | |
| User entered 'No (N)' | Brittany Belcher (b) (4) | 16 Feb 2021 16:37:58 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:57:13

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:07:34 |
| | | |
| User entered '2' | System | 16 Feb 2021 16:37:58 |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:57:13

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:07:34 |
| | | |
| User entered '1' | System | 16 Feb 2021 16:37:58 |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:57:13

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:07:34 |
| | | |
| User entered '804 (804)' | System | 16 Feb 2021 16:37:58 |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:57:13

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:08:03 |
| | | |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:02:55 |
| | (b) (4) | |
| User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS, ATC: MACROLIDES, PRODUCT: AZITHROMYCIN, PRODUCTSYNONYM: ZITHROMAX - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 16 Feb 2021 19:26:02 |
| | (b) (4) | |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 16 Feb 2021 19:26:02 |
| | (b) (4) | |
| Data point term sent to Coder | System | 16 Feb 2021 16:39:24 |
| User entered 'Zithromax' | Brittany Belcher (b) (4) | 16 Feb 2021 16:39:13 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:57:13

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:08:03 |
| | | |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:02:55 |
| | (b) (4) | |
| User entered 'No (N)' | Brittany Belcher (b) (4) | 16 Feb 2021 16:39:13 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:57:13

[Indication](#)

| Audit | User | Time (GMT) |
|------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:08:03 |
| | | |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:02:55 |
| | (b) (4) | |
| User entered 'Tooth Abscess' | Brittany Belcher (b) (4) | 16 Feb 2021 16:39:13 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:57:13

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:08:03 |
| | | |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:02:55 |
| | (b) (4) | |
| User entered '500' | Brittany Belcher (b) (4) | 16 Feb 2021 16:39:13 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:57:13

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:08:03 |
| | | |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:02:55 |
| | (b) (4) | |
| User entered 'mg (mg)' | Brittany Belcher (b) (4) | 16 Feb 2021 16:39:13 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:57:13

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:08:03 |
| | | |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:02:55 |
| | (b) (4) | |
| User entered empty. | Brittany Belcher (b) (4) | 16 Feb 2021 16:39:13 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:57:13

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:08:03 |
| | | |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:02:55 |
| | (b) (4) | |
| User entered 'once daily (QD)' | Brittany Belcher (b) (4) | 16 Feb 2021 16:39:13 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:57:13

If frequency is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:08:03 |
| | | |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:02:55 |
| | (b) (4) | |
| User entered empty. | Brittany Belcher (b) (4) | 16 Feb 2021 16:39:13 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:57:13

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:08:03 |
| | | |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:02:55 |
| | (b) (4) | |
| User entered 'Oral (ORAL)' | Brittany Belcher (b) (4) | 16 Feb 2021 16:39:13 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:57:13

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:08:03 |
| | | |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:02:55 |
| | (b) (4) | |
| User entered empty. | Brittany Belcher (b) (4) | 16 Feb 2021 16:39:13 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:57:13

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:08:03 |
| | | |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:02:55 |
| | (b) (4) | |
| User entered '19 Jan 2021' | Brittany Belcher (b) (4) | 16 Feb 2021 16:39:13 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:57:13

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:08:03 |
| | | |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:02:55 |
| | (b) (4) | |
| User entered '0' | Brittany Belcher (b) (4) | 16 Feb 2021 16:39:13 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:57:13

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:08:03 |
| | | |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:02:55 |
| | (b) (4) | |
| User entered 'No (N)' | Brittany Belcher (b) (4) | 16 Feb 2021 16:39:13 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:57:13

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:08:03 |
| | | |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:02:55 |
| | (b) (4) | |
| User entered '19 Jan 2021' | Brittany Belcher (b) (4) | 16 Feb 2021 16:39:13 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:57:13

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:08:03 |
| | | |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:02:55 |
| | (b) (4) | |
| User entered 'No (N)' | Brittany Belcher (b) (4) | 16 Feb 2021 16:39:13 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:57:13

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:08:03 |
| | | |
| User entered '1' | System | 16 Feb 2021 16:39:13 |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:57:13

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:08:03 |
| | | |
| User entered '1' | System | 16 Feb 2021 16:39:13 |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:57:13

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:08:03 |
| | | |
| User entered '804 (804)' | System | 16 Feb 2021 16:39:13 |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:57:13

Name of Medication

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:08:07 |
| | | |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:02:55 |
| | (b) (4) | |
| User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS, ATC: MACROLIDES, PRODUCT: AZITHROMYCIN, PRODUCTSYNONYM: ZITHROMAX - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 16 Feb 2021 19:26:02 |
| | (b) (4) | |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 16 Feb 2021 19:26:02 |
| | (b) (4) | |
| Data point term sent to Coder | System | 16 Feb 2021 16:40:25 |
| User entered 'Zithromax' | Brittany Belcher (b) (4) | 16 Feb 2021 16:39:57 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:57:13

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:08:07 |
| | | |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:02:55 |
| | (b) (4) | |
| User entered 'No (N)' | Brittany Belcher (b) (4) | 16 Feb 2021 16:39:57 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:57:13

[Indication](#)

| Audit | User | Time (GMT) |
|-----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:08:07 |
| | | |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:02:55 |
| | (b) (4) | |
| User entered 'Tooth Abcess' | Brittany Belcher (b) (4) | 16 Feb 2021 16:39:57 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:57:13

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:08:07 |
| | | |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:02:55 |
| | (b) (4) | |
| User entered '250' | Brittany Belcher (b) (4) | 16 Feb 2021 16:39:57 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:57:13

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:08:07 |
| | | |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:02:55 |
| | (b) (4) | |
| User entered 'mg (mg)' | Brittany Belcher (b) (4) | 16 Feb 2021 16:39:57 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:57:13

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:08:07 |
| | | |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:02:55 |
| | (b) (4) | |
| User entered empty. | Brittany Belcher (b) (4) | 16 Feb 2021 16:39:57 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:57:13

[Frequency](#)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:08:07 |
| | | |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:02:55 |
| | (b) (4) | |
| User closed query 'Data is required. Please complete.' (Site from System). | System | 16 Feb 2021 16:40:08 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 16 Feb 2021 16:40:08 |
| User entered 'once daily (QD)' reason for change: Data Entry Error | Brittany Belcher (b) (4) | 16 Feb 2021 16:40:08 |
| | | |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 16 Feb 2021 16:39:57 |
| User entered empty. | Brittany Belcher (b) (4) | 16 Feb 2021 16:39:57 |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:57:13

If frequency is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:08:07 |
| | | |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:02:55 |
| | (b) (4) | |
| User entered empty. | Brittany Belcher (b) (4) | 16 Feb 2021 16:39:57 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:57:13

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:08:07 |
| | | |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:02:55 |
| | (b) (4) | |
| User entered 'Oral (ORAL)' | Brittany Belcher (b) (4) | 16 Feb 2021 16:39:57 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:57:13

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:08:07 |
| | | |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:02:55 |
| | (b) (4) | |
| User entered empty. | Brittany Belcher (b) (4) | 16 Feb 2021 16:39:57 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:57:13

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:08:07 |
| | | |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:02:55 |
| | (b) (4) | |
| User entered '20 Jan 2021' | Brittany Belcher (b) (4) | 16 Feb 2021 16:39:57 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:57:13

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:08:07 |
| | | |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:02:55 |
| | (b) (4) | |
| User entered '0' | Brittany Belcher (b) (4) | 16 Feb 2021 16:39:57 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:57:13

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:08:07 |
| | | |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:02:55 |
| | (b) (4) | |
| User entered 'No (N)' | Brittany Belcher (b) (4) | 16 Feb 2021 16:39:57 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:57:13

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:08:07 |
| | | |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:02:55 |
| | (b) (4) | |
| User entered '30 Jan 2021' | Brittany Belcher (b) (4) | 16 Feb 2021 16:39:57 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:57:13

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:08:07 |
| | | |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:02:55 |
| | (b) (4) | |
| User entered 'No (N)' | Brittany Belcher (b) (4) | 16 Feb 2021 16:39:57 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:57:13

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:08:07 |
| | | |
| User entered '1' | System | 16 Feb 2021 16:40:08 |
| User entered empty. | System | 16 Feb 2021 16:39:57 |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:57:13

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:08:07 |
| | | |
| User entered '1' | System | 16 Feb 2021 16:40:08 |
| User entered empty. | System | 16 Feb 2021 16:39:57 |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:57:13

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:08:07 |
| | | |
| User entered '804 (804)' | System | 16 Feb 2021 16:40:08 |
| User entered empty. | System | 16 Feb 2021 16:39:57 |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:57:13

Name of Medication

| Audit | User | Time (GMT) |
|---|--|----------------------|
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: COLECALCIFEROL, PRODUCTSYNONYM: VITAMIN D [COLECALCIFEROL] - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 16 Apr 2021 12:45:54 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 16 Apr 2021 12:45:54 |
| Data point term sent to Coder | System | 15 Apr 2021 15:29:12 |
| Coding entries removed. | Brittany Belcher (b) (4) (b) (4) (b) (4) | 15 Apr 2021 15:28:46 |
| User signature succeeded. | Gregory Feldman (b) (4) (b) (4) | 09 Apr 2021 12:37:50 |
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: COLECALCIFEROL, PRODUCTSYNONYM: VITAMIN D [COLECALCIFEROL] - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 05 Apr 2021 14:50:25 |
| 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 Apr 2021 14:50:25 |
| Data point term sent to Coder | System | 05 Apr 2021 14:33:36 |
| Data point term sent to Coder | System | 05 Apr 2021 14:32:35 |
| User entered 'Vitamin D (Cholecalciferol)' | Brittany Belcher (b) (4) (b) (4) (b) (4) | 05 Apr 2021 14:32:04 |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:57:13

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered 'No (N)' | Brittany Belcher (b) (4) | 05 Apr 2021 14:32:04 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:57:13

[Indication](#)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| Signature has been broken. | (b) (4) | |
| | Brittany Belcher (b) (4) | 15 Apr 2021 15:28:46 |
| | (b) (4) | |
| User entered 'Coronary Artery Disease' reason for change: Data Entry Error | Brittany Belcher (b) (4) | 15 Apr 2021 15:28:46 |
| | (b) (4) | |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered 'MYOCARDIAL INFARCTION (SAE)' reason for change: Data Entry Error | Brittany Belcher (b) (4) | 05 Apr 2021 14:33:20 |
| | (b) (4) | |
| User entered 'Myocardial Infarction (AE)' | Brittany Belcher (b) (4) | 05 Apr 2021 14:32:04 |
| | (b) (4) | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:57:13

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered '4,000' | Brittany Belcher (b) (4) | 05 Apr 2021 14:32:04 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:57:13

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered 'IU (IU)' | Brittany Belcher (b) (4) | 05 Apr 2021 14:32:04 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:57:13

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered empty. | Brittany Belcher (b) (4) | 05 Apr 2021 14:32:04 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:57:13

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered 'once daily (QD)' | Brittany Belcher (b) (4) | 05 Apr 2021 14:32:04 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:57:13

If frequency is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered empty. | Brittany Belcher (b) (4) | 05 Apr 2021 14:32:04 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:57:13

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered 'Oral (ORAL)' | Brittany Belcher (b) (4) | 05 Apr 2021 14:32:04 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:57:13

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered empty. | Brittany Belcher (b) (4) | 05 Apr 2021 14:32:04 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:57:13

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered '19 Feb 2021' | Brittany Belcher (b) (4) | 05 Apr 2021 14:32:04 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:57:13

Start date completely unknown

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered '0' | Brittany Belcher (b) (4) | 05 Apr 2021 14:32:04 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:57:13

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Brittany Belcher (b) (4) | 05 Apr 2021 14:32:04 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:57:13

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered empty. | Brittany Belcher (b) (4) | 05 Apr 2021 14:32:04 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:57:13

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered 'No (N)' | Brittany Belcher (b) (4) | 05 Apr 2021 14:32:04 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:57:13

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 05 Apr 2021 14:32:04 |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:57:13

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 05 Apr 2021 14:32:04 |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:57:13

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 05 Apr 2021 14:32:04 |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:57:13

Name of Medication

| Audit | User | Time (GMT) |
|---|--|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: ALPHA AND BETA BLOCKING AGENTS, PRODUCT: CARVEDILOL - version WHODrug-Global-B3\\202003. | (b) (4) Coder Import (b) (4) (b) (4) | 05 Apr 2021 14:40:25 |
| 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 Apr 2021 14:40:25 |
| Data point term sent to Coder | System | 05 Apr 2021 14:33:35 |
| User entered 'Carvedilol' | Brittany Belcher (b) (4) (b) (4) (b) (4) | 05 Apr 2021 14:33:01 |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:57:13

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered 'No (N)' | Brittany Belcher (b) (4) | 05 Apr 2021 14:33:01 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:57:13

[Indication](#)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered 'Congestive Heart Failure (AE)' | Brittany Belcher (b) (4) | 05 Apr 2021 14:33:01 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:57:13

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| | (b) (4) | |
| Signature has been broken. | Brittany Belcher (b) (4) | 15 Apr 2021 15:38:19 |
| | | |
| User entered '6.25' reason for change: Data Entry Error | Brittany Belcher (b) (4) | 15 Apr 2021 15:38:19 |
| | | |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered '12.5' | Brittany Belcher (b) (4) | 05 Apr 2021 14:33:01 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:57:13

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered 'mg (mg)' | Brittany Belcher (b) (4) | 05 Apr 2021 14:33:01 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:57:13

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered empty. | Brittany Belcher (b) (4) | 05 Apr 2021 14:33:01 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:57:13

[Frequency](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered 'twice daily (BID)' | Brittany Belcher (b) (4) | 05 Apr 2021 14:33:01 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:57:13

If frequency is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered empty. | Brittany Belcher (b) (4) | 05 Apr 2021 14:33:01 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:57:13

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered 'Oral (ORAL)' | Brittany Belcher (b) (4) | 05 Apr 2021 14:33:01 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:57:13

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered empty. | Brittany Belcher (b) (4) | 05 Apr 2021 14:33:01 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:57:13

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered '19 Feb 2021' | Brittany Belcher (b) (4) | 05 Apr 2021 14:33:01 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:57:13

Start date completely unknown

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered '0' | Brittany Belcher (b) (4) | 05 Apr 2021 14:33:01 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:57:13

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Brittany Belcher (b) (4) | 05 Apr 2021 14:33:01 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:57:13

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered empty. | Brittany Belcher (b) (4) | 05 Apr 2021 14:33:01 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:57:13

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered 'No (N)' | Brittany Belcher (b) (4) | 05 Apr 2021 14:33:01 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:57:13

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '2' | System | 05 Apr 2021 14:33:01 |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:57:13

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 05 Apr 2021 14:33:01 |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:57:13

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 05 Apr 2021 14:33:01 |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:57:13

Name of Medication

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:10:32 |
| | | |
| User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: ENOXAPARIN SODIUM, PRODUCTSYNONYM: LOVENOX [ENOXAPARIN SODIUM] - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 15 Apr 2021 15:38:25 |
| | (b) (4) | |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 15 Apr 2021 15:38:25 |
| | (b) (4) | |
| Data point term sent to Coder | System | 15 Apr 2021 15:36:18 |
| Coding entries removed. | Brittany Belcher (b) (4) | 15 Apr 2021 15:35:44 |
| | | |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: ENOXAPARIN SODIUM, PRODUCTSYNONYM: LOVENOX [ENOXAPARIN SODIUM] - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 06 Apr 2021 12:31:59 |
| | (b) (4) | |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 06 Apr 2021 12:31:59 |
| | (b) (4) | |
| Data point term sent to Coder | System | 06 Apr 2021 12:31:16 |
| User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: ENOXAPARIN SODIUM, PRODUCTSYNONYM: LOVENOX [ENOXAPARIN SODIUM] - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 06 Apr 2021 12:30:57 |
| | (b) (4) | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:57:13

Name of Medication

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003. | Coder Import (b) (4) | 06 Apr 2021 12:30:57 |
| Query 'DM-Coding: This medication can be referred as multiple ingredients in the standard coding dictionary. Please enter all the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. Thank you. ' canceled (Site from System). | Coder Import (b) (4) | 06 Apr 2021 12:30:43 |
| User opened query 'DM-Coding: This medication can be referred as multiple ingredients in the standard coding dictionary. Please enter all the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. Thank you. ' (Site from System). | Coder Import (b) (4) | 05 Apr 2021 14:43:16 |
| Data point term sent to Coder | System | 05 Apr 2021 14:35:37 |
| User entered 'Lovenox' | Brittany Belcher (b) (4) | 05 Apr 2021 14:34:44 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:57:13

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:10:32 |
| | | |
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| | (b) (4) | |
| Signature has been broken. | Brittany Belcher (b) (4) | 15 Apr 2021 15:35:44 |
| | | |
| User entered 'Yes (Y)' reason for change: Data Entry Error | Brittany Belcher (b) (4) | 15 Apr 2021 15:35:44 |
| | | |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered 'No (N)' | Brittany Belcher (b) (4) | 05 Apr 2021 14:34:44 |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:57:13

[Indication](#)

| Audit | User | Time (GMT) |
|---|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:10:32 |
| | | |
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| | (b) (4) | |
| Signature has been broken. | Brittany Belcher (b) (4) | 15 Apr 2021 15:35:44 |
| | | |
| User entered 'DVT Prophylaxis' reason for change: | Brittany Belcher (b) (4) | 15 Apr 2021 15:35:44 |
| Data Entry Error | | |
| | | |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered 'Coronary Artery Disease (CAD)' | Brittany Belcher (b) (4) | 05 Apr 2021 14:34:44 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:57:13

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:10:32 |
| | | |
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| | (b) (4) | |
| Signature has been broken. | Brittany Belcher (b) (4) | 15 Apr 2021 15:35:44 |
| | | |
| User entered '40' reason for change: Data Entry Error | Brittany Belcher (b) (4) | 15 Apr 2021 15:35:44 |
| | | |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered '150' | Brittany Belcher (b) (4) | 05 Apr 2021 14:34:44 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:57:13

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:10:32 |
| | | |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered 'mg (mg)' | Brittany Belcher (b) (4) | 05 Apr 2021 14:34:44 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:57:13

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:10:32 |
| | | |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered empty. | Brittany Belcher (b) (4) | 05 Apr 2021 14:34:44 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:57:13

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:10:32 |
| | | |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered 'once daily (QD)' | Brittany Belcher (b) (4) | 05 Apr 2021 14:34:44 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:57:13

If frequency is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:10:32 |
| | | |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered empty. | Brittany Belcher (b) (4) | 05 Apr 2021 14:34:44 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:57:13

[Route of administration](#)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:10:32 |
| | | |
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| | (b) (4) | |
| Signature has been broken. | Brittany Belcher (b) (4) | 15 Apr 2021 15:35:44 |
| | | |
| User entered 'Subcutaneous (SUBCUTANEOUS)' reason for change: Data Entry Error | Brittany Belcher (b) (4) | 15 Apr 2021 15:35:44 |
| | | |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered 'Intravenous (INTRAVENOUS)' | Brittany Belcher (b) (4) | 05 Apr 2021 14:34:44 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:57:13

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:10:32 |
| | | |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered empty. | Brittany Belcher (b) (4) | 05 Apr 2021 14:34:44 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:57:13

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:10:32 |
| | | |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered '19 Feb 2021' | Brittany Belcher (b) (4) | 05 Apr 2021 14:34:44 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:57:13

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:10:32 |
| | | |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered '0' | Brittany Belcher (b) (4) | 05 Apr 2021 14:34:44 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:57:13

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:10:32 |
| | | |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered 'No (N)' | Brittany Belcher (b) (4) | 05 Apr 2021 14:34:44 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:57:13

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:10:32 |
| | | |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered '22 Feb 2021' | Brittany Belcher (b) (4) | 05 Apr 2021 14:34:44 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:57:13

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:10:32 |
| | | |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered 'No (N)' | Brittany Belcher (b) (4) | 05 Apr 2021 14:34:44 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:57:13

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:10:32 |
| | | |
| User entered '1' | System | 05 Apr 2021 14:34:44 |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:57:13

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:10:32 |
| | | |
| User entered '1' | System | 05 Apr 2021 14:34:44 |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:57:13

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:10:32 |
| | | |
| User entered '804 (804)' | System | 05 Apr 2021 14:34:44 |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:57:13

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--|--|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003. | (b) (4) Coder Import (b) (4) (b) (4) | 05 Apr 2021 14:37:19 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 05 Apr 2021 14:37:19 |
| Data point term sent to Coder | System | 05 Apr 2021 14:36:37 |
| User entered 'Atrovastatin' | Brittany Belcher (b) (4) (b) (4) (b) (4) | 05 Apr 2021 14:35:54 |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:57:13

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered 'No (N)' | Brittany Belcher (b) (4) | 05 Apr 2021 14:35:54 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:57:13

[Indication](#)

| Audit | User | Time (GMT) |
|-------------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered 'Hyperlipidemia' | Brittany Belcher (b) (4) | 05 Apr 2021 14:35:54 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:57:13

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered '40' | Brittany Belcher (b) (4) | 05 Apr 2021 14:35:54 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:57:13

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered 'mg (mg)' | Brittany Belcher (b) (4) | 05 Apr 2021 14:35:54 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:57:13

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered empty. | Brittany Belcher (b) (4) | 05 Apr 2021 14:35:54 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:57:13

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered 'once daily (QD)' | Brittany Belcher (b) (4) | 05 Apr 2021 14:35:54 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:57:13

If frequency is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered empty. | Brittany Belcher (b) (4) | 05 Apr 2021 14:35:54 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:57:13

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered 'Oral (ORAL)' | Brittany Belcher (b) (4) | 05 Apr 2021 14:35:54 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:57:13

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered empty. | Brittany Belcher (b) (4) | 05 Apr 2021 14:35:54 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:57:13

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered '19 Feb 2021' | Brittany Belcher (b) (4) | 05 Apr 2021 14:35:54 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:57:13

Start date completely unknown

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered '0' | Brittany Belcher (b) (4) | 05 Apr 2021 14:35:54 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:57:13

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Brittany Belcher (b) (4) | 05 Apr 2021 14:35:54 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:57:13

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered empty. | Brittany Belcher (b) (4) | 05 Apr 2021 14:35:54 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:57:13

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered 'No (N)' | Brittany Belcher (b) (4) | 05 Apr 2021 14:35:54 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:57:13

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 05 Apr 2021 14:35:54 |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:57:13

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 05 Apr 2021 14:35:54 |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:57:13

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 05 Apr 2021 14:35:54 |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:57:13

Name of Medication

| Audit | User | Time (GMT) |
|---|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:12:10 |
| | | |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID;CLOPIDOGREL, PRODUCTSYNONYM: ASPIRIN;CLOPIDOGREL - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 06 Apr 2021 12:14:54 |
| | (b) (4) | |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 06 Apr 2021 12:14:54 |
| | (b) (4) | |
| Data point term sent to Coder | System | 05 Apr 2021 14:37:38 |
| User entered 'Clopidogrel/ Aspirin' | Brittany Belcher (b) (4) | 05 Apr 2021 14:37:28 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:57:13

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:12:10 |
| | | |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered 'No (N)' | Brittany Belcher (b) (4) | 05 Apr 2021 14:37:28 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:57:13

[Indication](#)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:12:10 |
| | | |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered 'Coronary Artery Disease (CAD)' | Brittany Belcher (b) (4) | 05 Apr 2021 14:37:28 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:57:13

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:12:10 |
| | | |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered '150' | Brittany Belcher (b) (4) | 05 Apr 2021 14:37:28 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:57:13

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:12:10 |
| | | |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered 'mg (mg)' | Brittany Belcher (b) (4) | 05 Apr 2021 14:37:28 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:57:13

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:12:10 |
| | | |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered empty. | Brittany Belcher (b) (4) | 05 Apr 2021 14:37:28 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:57:13

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:12:10 |
| | | |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered 'once daily (QD)' | Brittany Belcher (b) (4) | 05 Apr 2021 14:37:28 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:57:13

If frequency is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:12:10 |
| | | |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered empty. | Brittany Belcher (b) (4) | 05 Apr 2021 14:37:28 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:57:13

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:12:10 |
| | | |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered 'Oral (ORAL)' | Brittany Belcher (b) (4) | 05 Apr 2021 14:37:28 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:57:13

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:12:10 |
| | | |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered empty. | Brittany Belcher (b) (4) | 05 Apr 2021 14:37:28 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:57:13

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:12:10 |
| | | |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered '19 Feb 2021' | Brittany Belcher (b) (4) | 05 Apr 2021 14:37:28 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:57:13

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:12:10 |
| | | |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered '0' | Brittany Belcher (b) (4) | 05 Apr 2021 14:37:28 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:57:13

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:12:10 |
| | | |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered 'No (N)' | Brittany Belcher (b) (4) | 05 Apr 2021 14:37:28 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:57:13

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:12:10 |
| | | |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered '19 Feb 2021' | Brittany Belcher (b) (4) | 05 Apr 2021 14:37:28 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:57:13

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:12:10 |
| | | |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered 'No (N)' | Brittany Belcher (b) (4) | 05 Apr 2021 14:37:28 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:57:13

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:12:10 |
| | | |
| User entered 'I' | System | 05 Apr 2021 14:37:28 |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:57:13

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:12:10 |
| | | |
| User entered '1' | System | 05 Apr 2021 14:37:28 |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:57:13

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:12:10 |
| | | |
| User entered '804 (804)' | System | 05 Apr 2021 14:37:28 |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:57:13

Name of Medication

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:10:45 |
| | | |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| 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: GLUCOCORTICIDS, PRODUCT: HYDROCORTISONE SODIUM SUCCINATE, PRODUCTSYNONYM: SOLUCORTEF - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 05 Apr 2021 15:05:16 |
| | (b) (4) | |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 05 Apr 2021 15:05:16 |
| | (b) (4) | |
| Data point term sent to Coder | System | 05 Apr 2021 14:39:39 |
| User entered 'Solu-Cortef' | Brittany Belcher (b) (4) | 05 Apr 2021 14:39:15 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:57:13

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:10:45 |
| | | |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered 'No (N)' | Brittany Belcher (b) (4) | 05 Apr 2021 14:39:15 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:57:13

[Indication](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:10:45 |
| | | |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered 'Heart Cath' | Brittany Belcher (b) (4) | 05 Apr 2021 14:39:15 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:57:13

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:10:45 |
| | | |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered '200' | Brittany Belcher (b) (4) | 05 Apr 2021 14:39:15 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:57:13

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:10:45 |
| | | |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered 'mg (mg)' | Brittany Belcher (b) (4) | 05 Apr 2021 14:39:15 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:57:13

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:10:45 |
| | | |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered empty. | Brittany Belcher (b) (4) | 05 Apr 2021 14:39:15 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:57:13

[Frequency](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:10:45 |
| | | |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered 'once (ONCE)' | Brittany Belcher (b) (4) | 05 Apr 2021 14:39:15 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:57:13

If frequency is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:10:45 |
| | | |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered empty. | Brittany Belcher (b) (4) | 05 Apr 2021 14:39:15 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:57:13

[Route of administration](#)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:10:45 |
| | | |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered 'Intravenous (INTRAVENOUS)' | Brittany Belcher (b) (4) | 05 Apr 2021 14:39:15 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:57:13

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:10:45 |
| | | |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered empty. | Brittany Belcher (b) (4) | 05 Apr 2021 14:39:15 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:57:13

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:10:45 |
| | | |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered '20 Feb 2021' | Brittany Belcher (b) (4) | 05 Apr 2021 14:39:15 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:57:13

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:10:45 |
| | | |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered '0' | Brittany Belcher (b) (4) | 05 Apr 2021 14:39:15 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:57:13

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:10:45 |
| | | |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered 'No (N)' | Brittany Belcher (b) (4) | 05 Apr 2021 14:39:15 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:57:13

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:10:45 |
| | | |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered '20 Feb 2021' | Brittany Belcher (b) (4) | 05 Apr 2021 14:39:15 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:57:13

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:10:45 |
| | | |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered 'No (N)' | Brittany Belcher (b) (4) | 05 Apr 2021 14:39:15 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:57:13

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:10:45 |
| | | |
| User entered empty. | System | 05 Apr 2021 14:39:15 |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:57:13

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:10:45 |
| | | |
| User entered empty. | System | 05 Apr 2021 14:39:15 |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:57:13

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:10:45 |
| | | |
| User entered empty. | System | 05 Apr 2021 14:39:15 |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:57:13

Name of Medication

| Audit | User | Time (GMT) |
|---|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:11:54 |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: AMINOALKYL ETHERS, PRODUCT: DIPHENHYDRAMINE HYDROCHLORIDE, PRODUCTSYNONYM: BENADRYL [DIPHENHYDRAMINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 06 Apr 2021 12:08:46 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 06 Apr 2021 12:08:46 |
| Data point term sent to Coder | System | 05 Apr 2021 14:40:40 |
| User entered 'BENADRYL' reason for change: Data Entry Error | Brittany Belcher (b) (4) | 05 Apr 2021 14:40:03 |
| User entered 'Benadry' | Brittany Belcher (b) (4) | 05 Apr 2021 14:39:56 |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:57:13

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:11:54 |
| | | |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered 'No (N)' | Brittany Belcher (b) (4) | 05 Apr 2021 14:39:56 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:57:13

[Indication](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:11:54 |
| | | |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered 'Heart Cath' | Brittany Belcher (b) (4) | 05 Apr 2021 14:39:56 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:57:13

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:11:54 |
| | | |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered '50' | Brittany Belcher (b) (4) | 05 Apr 2021 14:39:56 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:57:13

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:11:54 |
| | | |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered 'mg (mg)' | Brittany Belcher (b) (4) | 05 Apr 2021 14:39:56 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:57:13

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:11:54 |
| | | |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered empty. | Brittany Belcher (b) (4) | 05 Apr 2021 14:39:56 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:57:13

[Frequency](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:11:54 |
| | | |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered 'once (ONCE)' | Brittany Belcher (b) (4) | 05 Apr 2021 14:39:56 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:57:13

If frequency is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:11:54 |
| | | |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered empty. | Brittany Belcher (b) (4) | 05 Apr 2021 14:39:56 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:57:13

[Route of administration](#)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:11:54 |
| | | |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered 'Intravenous (INTRAVENOUS)' | Brittany Belcher (b) (4) | 05 Apr 2021 14:39:56 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:57:13

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:11:54 |
| | | |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered empty. | Brittany Belcher (b) (4) | 05 Apr 2021 14:39:56 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:57:13

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:11:54 |
| | | |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered '20 Feb 2021' | Brittany Belcher (b) (4) | 05 Apr 2021 14:39:56 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:57:13

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:11:54 |
| | | |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered '0' | Brittany Belcher (b) (4) | 05 Apr 2021 14:39:56 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:57:13

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:11:54 |
| | | |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered 'No (N)' | Brittany Belcher (b) (4) | 05 Apr 2021 14:39:56 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:57:13

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:11:54 |
| | | |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered '20 Feb 2021' | Brittany Belcher (b) (4) | 05 Apr 2021 14:39:56 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:57:13

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:11:54 |
| | | |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered 'No (N)' | Brittany Belcher (b) (4) | 05 Apr 2021 14:39:56 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:57:13

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:11:54 |
| | | |
| User entered empty. | System | 05 Apr 2021 14:39:56 |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:57:13

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:11:54 |
| | | |
| User entered empty. | System | 05 Apr 2021 14:39:56 |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:57:13

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:11:54 |
| | | |
| User entered empty. | System | 05 Apr 2021 14:39:56 |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:57:13

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:10:58 |
| | | |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, GENERAL, ATC: OPIOID ANESTHETICS, PRODUCT: FENTANYL - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 05 Apr 2021 15:19:26 |
| | (b) (4) | |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 05 Apr 2021 15:19:26 |
| | (b) (4) | |
| Data point term sent to Coder | System | 05 Apr 2021 14:41:41 |
| User entered 'Fentanyl' | Brittany Belcher (b) (4) | 05 Apr 2021 14:40:46 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:57:13

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:10:58 |
| | | |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered 'No (N)' | Brittany Belcher (b) (4) | 05 Apr 2021 14:40:46 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:57:13

[Indication](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:10:58 |
| | | |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered 'Heart Cath' | Brittany Belcher (b) (4) | 05 Apr 2021 14:40:46 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:57:13

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:10:58 |
| | | |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered '50' | Brittany Belcher (b) (4) | 05 Apr 2021 14:40:46 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:57:13

[Dose unit](#)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:10:58 |
| | | |
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| | (b) (4) | |
| Signature has been broken. | Brittany Belcher (b) (4) | 15 Apr 2021 15:41:12 |
| | | |
| User entered 'ug (ug)' reason for change: Data Entry Error | Brittany Belcher (b) (4) | 15 Apr 2021 15:41:12 |
| | | |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered 'mg (mg)' | Brittany Belcher (b) (4) | 05 Apr 2021 14:40:46 |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:57:13

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:10:58 |
| | | |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered empty. | Brittany Belcher (b) (4) | 05 Apr 2021 14:40:46 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:57:13

[Frequency](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:10:58 |
| | | |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered 'once (ONCE)' | Brittany Belcher (b) (4) | 05 Apr 2021 14:40:46 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:57:13

If frequency is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:10:58 |
| | | |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered empty. | Brittany Belcher (b) (4) | 05 Apr 2021 14:40:46 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:57:13

[Route of administration](#)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:10:58 |
| | | |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered 'Intravenous (INTRAVENOUS)' | Brittany Belcher (b) (4) | 05 Apr 2021 14:40:46 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:57:13

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:10:58 |
| | | |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered empty. | Brittany Belcher (b) (4) | 05 Apr 2021 14:40:46 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:57:13

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:10:58 |
| | | |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered '20 Feb 2021' | Brittany Belcher (b) (4) | 05 Apr 2021 14:40:46 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:57:13

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:10:58 |
| | | |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered '0' | Brittany Belcher (b) (4) | 05 Apr 2021 14:40:46 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:57:13

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:10:58 |
| | | |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered 'No (N)' | Brittany Belcher (b) (4) | 05 Apr 2021 14:40:46 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:57:13

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:10:58 |
| | | |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered '20 Feb 2021' | Brittany Belcher (b) (4) | 05 Apr 2021 14:40:46 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:57:13

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:10:58 |
| | | |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered 'No (N)' | Brittany Belcher (b) (4) | 05 Apr 2021 14:40:46 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:57:13

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:10:58 |
| | | |
| User entered empty. | System | 05 Apr 2021 14:40:46 |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:57:13

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:10:58 |
| | | |
| User entered empty. | System | 05 Apr 2021 14:40:46 |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:57:13

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:10:58 |
| | | |
| User entered empty. | System | 05 Apr 2021 14:40:46 |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:57:13

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:11:11 |
| | | |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: MIDAZOLAM HYDROCHLORIDE, PRODUCTSYNONYM: VERSED - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 06 Apr 2021 03:52:50 |
| | (b) (4) | |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 06 Apr 2021 03:52:50 |
| | (b) (4) | |
| Data point term sent to Coder | System | 05 Apr 2021 14:41:41 |
| User entered 'Versed' | Brittany Belcher (b) (4) | 05 Apr 2021 14:41:24 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:57:13

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:11:11 |
| | | |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered 'No (N)' | Brittany Belcher (b) (4) | 05 Apr 2021 14:41:24 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:57:13

[Indication](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:11:11 |
| | | |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered 'Heart Cath' | Brittany Belcher (b) (4) | 05 Apr 2021 14:41:24 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:57:13

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:11:11 |
| | | |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered '2' | Brittany Belcher (b) (4) | 05 Apr 2021 14:41:24 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:57:13

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:11:11 |
| | | |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered 'mg (mg)' | Brittany Belcher (b) (4) | 05 Apr 2021 14:41:24 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:57:13

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:11:11 |
| | | |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered empty. | Brittany Belcher (b) (4) | 05 Apr 2021 14:41:24 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:57:13

[Frequency](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:11:11 |
| | | |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered 'once (ONCE)' | Brittany Belcher (b) (4) | 05 Apr 2021 14:41:24 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:57:13

If frequency is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:11:11 |
| | | |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered empty. | Brittany Belcher (b) (4) | 05 Apr 2021 14:41:24 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:57:13

[Route of administration](#)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:11:11 |
| | | |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered 'Intravenous (INTRAVENOUS)' | Brittany Belcher (b) (4) | 05 Apr 2021 14:41:24 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:57:13

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:11:11 |
| | | |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered empty. | Brittany Belcher (b) (4) | 05 Apr 2021 14:41:24 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:57:13

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:11:11 |
| | | |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered '20 Feb 2021' | Brittany Belcher (b) (4) | 05 Apr 2021 14:41:24 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:57:13

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:11:11 |
| | | |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered '0' | Brittany Belcher (b) (4) | 05 Apr 2021 14:41:24 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:57:13

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:11:11 |
| | | |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered 'No (N)' | Brittany Belcher (b) (4) | 05 Apr 2021 14:41:24 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:57:13

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:11:11 |
| | | |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered '20 Feb 2021' | Brittany Belcher (b) (4) | 05 Apr 2021 14:41:24 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:57:13

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:11:11 |
| | | |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered 'No (N)' | Brittany Belcher (b) (4) | 05 Apr 2021 14:41:24 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:57:13

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:11:11 |
| | | |
| User entered empty. | System | 05 Apr 2021 14:41:24 |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:57:13

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:11:11 |
| | | |
| User entered empty. | System | 05 Apr 2021 14:41:24 |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:57:13

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:11:11 |
| | | |
| User entered empty. | System | 05 Apr 2021 14:41:24 |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:57:13

[Name of Medication](#)

| Audit | User | Time (GMT) |
|---|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:11:30 |
| | | |
| User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, LOCAL, ATC: AMIDES, PRODUCT: LIDOCAINE - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 16 Apr 2021 14:45:04 |
| | (b) (4) | |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 16 Apr 2021 14:45:04 |
| | (b) (4) | |
| Data point term sent to Coder | System | 15 Apr 2021 15:42:22 |
| Coding entries removed. | Brittany Belcher (b) (4) | 15 Apr 2021 15:42:02 |
| | | |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: ANTIARRHYTHMICS, CLASS I AND III, ATC: ANTIARRHYTHMICS, CLASS IB, PRODUCT: LIDOCAINE - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 05 Apr 2021 14:58:16 |
| | (b) (4) | |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 05 Apr 2021 14:58:16 |
| | (b) (4) | |
| Data point term sent to Coder | System | 05 Apr 2021 14:42:42 |
| User entered 'Lidocaine' | Brittany Belcher (b) (4) | 05 Apr 2021 14:42:14 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:57:13

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:11:30 |
| | | |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered 'No (N)' | Brittany Belcher (b) (4) | 05 Apr 2021 14:42:14 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:57:13

[Indication](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:11:30 |
| | | |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered 'Heart Cath' | Brittany Belcher (b) (4) | 05 Apr 2021 14:42:14 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:57:13

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:11:30 |
| | | |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered 'I' | Brittany Belcher (b) (4) | 05 Apr 2021 14:42:14 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:57:13

[Dose unit](#)

| Audit | User | Time (GMT) |
|------------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:11:30 |
| | | |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered 'Other (OTHER)' | Brittany Belcher (b) (4) | 05 Apr 2021 14:42:14 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:57:13

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:11:30 |
| | | |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered 'percent (%)' | Brittany Belcher (b) (4) | 05 Apr 2021 14:42:14 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:57:13

[Frequency](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:11:30 |
| | | |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered 'once (ONCE)' | Brittany Belcher (b) (4) | 05 Apr 2021 14:42:14 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:57:13

If frequency is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:11:30 |
| | | |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered empty. | Brittany Belcher (b) (4) | 05 Apr 2021 14:42:14 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:57:13

[Route of administration](#)

| Audit | User | Time (GMT) |
|---|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:11:30 |
| | | |
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| | (b) (4) | |
| Signature has been broken. | Brittany Belcher (b) (4) | 15 Apr 2021 15:42:02 |
| | | |
| User entered 'Other (OTHER)' reason for change: Data Entry Error | Brittany Belcher (b) (4) | 15 Apr 2021 15:42:02 |
| | | |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered 'Intravenous (INTRAVENOUS)' | Brittany Belcher (b) (4) | 05 Apr 2021 14:42:14 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:57:13

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:11:30 |
| | | |
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| | (b) (4) | |
| Signature has been broken. | Brittany Belcher (b) (4) | 15 Apr 2021 15:42:02 |
| | | |
| User entered 'Local Injection' reason for change: Data Entry Error | Brittany Belcher (b) (4) | 15 Apr 2021 15:42:02 |
| | | |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered empty. | Brittany Belcher (b) (4) | 05 Apr 2021 14:42:14 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:57:13

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:11:30 |
| | | |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered '20 Feb 2021' | Brittany Belcher (b) (4) | 05 Apr 2021 14:42:14 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:57:13

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:11:30 |
| | | |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered '0' | Brittany Belcher (b) (4) | 05 Apr 2021 14:42:14 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:57:13

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:11:30 |
| | | |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered 'No (N)' | Brittany Belcher (b) (4) | 05 Apr 2021 14:42:14 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:57:13

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:11:30 |
| | | |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered '20 Feb 2021' | Brittany Belcher (b) (4) | 05 Apr 2021 14:42:14 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:57:13

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:11:30 |
| | | |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered 'No (N)' | Brittany Belcher (b) (4) | 05 Apr 2021 14:42:14 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:57:13

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:11:30 |
| | | |
| User entered empty. | System | 05 Apr 2021 14:42:14 |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:57:13

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:11:30 |
| | | |
| User entered empty. | System | 05 Apr 2021 14:42:14 |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:57:13

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 11:11:30 |
| | | |
| User entered empty. | System | 05 Apr 2021 14:42:14 |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:57:13

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN, PRODUCTSYNONYM: LIPITOR [ATORVASTATIN] - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 05 Apr 2021 14:44:26 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 05 Apr 2021 14:44:26 |
| Data point term sent to Coder | System | 05 Apr 2021 14:43:43 |
| User entered 'Lipitor' | Brittany Belcher (b) (4) | 05 Apr 2021 14:43:01 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:57:13

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered 'No (N)' | Brittany Belcher (b) (4) | 05 Apr 2021 14:43:01 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:57:13

[Indication](#)

| Audit | User | Time (GMT) |
|-------------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered 'Hyperlipidemia' | Brittany Belcher (b) (4) | 05 Apr 2021 14:43:01 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:57:13

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered '40' | Brittany Belcher (b) (4) | 05 Apr 2021 14:43:01 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:57:13

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered 'mg (mg)' | Brittany Belcher (b) (4) | 05 Apr 2021 14:43:01 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:57:13

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered empty. | Brittany Belcher (b) (4) | 05 Apr 2021 14:43:01 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:57:13

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered 'once daily (QD)' | Brittany Belcher (b) (4) | 05 Apr 2021 14:43:01 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:57:13

If frequency is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered empty. | Brittany Belcher (b) (4) | 05 Apr 2021 14:43:01 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:57:13

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered 'Oral (ORAL)' | Brittany Belcher (b) (4) | 05 Apr 2021 14:43:01 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:57:13

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered empty. | Brittany Belcher (b) (4) | 05 Apr 2021 14:43:01 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:57:13

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered '23 Feb 2021' | Brittany Belcher (b) (4) | 05 Apr 2021 14:43:01 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:57:13

Start date completely unknown

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered '0' | Brittany Belcher (b) (4) | 05 Apr 2021 14:43:01 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:57:13

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Brittany Belcher (b) (4) | 05 Apr 2021 14:43:01 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:57:13

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered empty. | Brittany Belcher (b) (4) | 05 Apr 2021 14:43:01 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:57:13

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered 'No (N)' | Brittany Belcher (b) (4) | 05 Apr 2021 14:43:01 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:57:13

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 05 Apr 2021 14:43:01 |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:57:13

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 05 Apr 2021 14:43:01 |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:57:13

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 05 Apr 2021 14:43:01 |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:57:13

Name of Medication

| Audit | User | Time (GMT) |
|---|------------------------------------|--|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: ALPHA AND BETA BLOCKING AGENTS, PRODUCT: CARVEDILOL - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 16 Apr 2021 01:22:06 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 16 Apr 2021 01:22:06 |
| Data point term sent to Coder Coding entries removed. | System Brittany Belcher (b) (4) | 15 Apr 2021 15:37:19 15 Apr 2021 15:36:46 |
| Signature has been broken. | Brittany Belcher (b) (4) | 15 Apr 2021 15:36:46 |
| User entered 'Carvedilol' reason for change: Data Entry Error | Brittany Belcher (b) (4) | 15 Apr 2021 15:36:46 |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: ALPHA AND BETA BLOCKING AGENTS, PRODUCT: CARVEDILOL, PRODUCTSYNONYM: COREG - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 05 Apr 2021 14:45:28 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 05 Apr 2021 14:45:28 |
| Data point term sent to Coder User entered 'Coreg' | System Brittany Belcher (b) (4) | 05 Apr 2021 14:44:44 05 Apr 2021 14:43:46 |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:57:13

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered 'No (N)' | Brittany Belcher (b) (4) | 05 Apr 2021 14:43:46 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:57:13

[Indication](#)

| Audit | User | Time (GMT) |
|---|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered 'Congestive Heart Failure (CHF)' | Brittany Belcher (b) (4) | 05 Apr 2021 14:43:46 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:57:13

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered '12.5' | Brittany Belcher (b) (4) | 05 Apr 2021 14:43:46 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:57:13

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered 'mg (mg)' | Brittany Belcher (b) (4) | 05 Apr 2021 14:43:46 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:57:13

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered empty. | Brittany Belcher (b) (4) | 05 Apr 2021 14:43:46 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:57:13

[Frequency](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered 'twice daily (BID)' | Brittany Belcher (b) (4) | 05 Apr 2021 14:43:46 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:57:13

If frequency is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered empty. | Brittany Belcher (b) (4) | 05 Apr 2021 14:43:46 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:57:13

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered 'Oral (ORAL)' | Brittany Belcher (b) (4) | 05 Apr 2021 14:43:46 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:57:13

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered empty. | Brittany Belcher (b) (4) | 05 Apr 2021 14:43:46 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:57:13

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered '23 Feb 2021' | Brittany Belcher (b) (4) | 05 Apr 2021 14:43:46 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:57:13

Start date completely unknown

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered '0' | Brittany Belcher (b) (4) | 05 Apr 2021 14:43:46 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:57:13

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Brittany Belcher (b) (4) | 05 Apr 2021 14:43:46 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:57:13

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered empty. | Brittany Belcher (b) (4) | 05 Apr 2021 14:43:46 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:57:13

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered 'No (N)' | Brittany Belcher (b) (4) | 05 Apr 2021 14:43:46 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:57:13

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '2' | System | 05 Apr 2021 14:43:46 |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:57:13

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 05 Apr 2021 14:43:46 |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:57:13

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 05 Apr 2021 14:43:46 |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:57:13

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 06 Apr 2021 04:32:44 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 06 Apr 2021 04:32:44 |
| Data point term sent to Coder | System | 05 Apr 2021 14:44:45 |
| User entered 'Aspirin' | Brittany Belcher (b) (4) | 05 Apr 2021 14:44:21 |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:57:13

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered 'No (N)' | Brittany Belcher (b) (4) | 05 Apr 2021 14:44:21 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:57:13

[Indication](#)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered 'Coronary Artery Disease (CAD)' | Brittany Belcher (b) (4) | 05 Apr 2021 14:44:21 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:57:13

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered '81' | Brittany Belcher (b) (4) | 05 Apr 2021 14:44:21 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:57:13

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered 'mg (mg)' | Brittany Belcher (b) (4) | 05 Apr 2021 14:44:21 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:57:13

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered empty. | Brittany Belcher (b) (4) | 05 Apr 2021 14:44:21 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:57:13

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered 'once daily (QD)' | Brittany Belcher (b) (4) | 05 Apr 2021 14:44:21 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:57:13

If frequency is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered empty. | Brittany Belcher (b) (4) | 05 Apr 2021 14:44:21 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:57:13

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered 'Oral (ORAL)' | Brittany Belcher (b) (4) | 05 Apr 2021 14:44:21 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:57:13

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered empty. | Brittany Belcher (b) (4) | 05 Apr 2021 14:44:21 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:57:13

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered '23 Feb 2021' | Brittany Belcher (b) (4) | 05 Apr 2021 14:44:21 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:57:13

Start date completely unknown

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered '0' | Brittany Belcher (b) (4) | 05 Apr 2021 14:44:21 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:57:13

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Brittany Belcher (b) (4) | 05 Apr 2021 14:44:21 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:57:13

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered empty. | Brittany Belcher (b) (4) | 05 Apr 2021 14:44:21 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:57:13

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered 'No (N)' | Brittany Belcher (b) (4) | 05 Apr 2021 14:44:21 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:57:13

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 05 Apr 2021 14:44:21 |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:57:13

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 05 Apr 2021 14:44:21 |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:57:13

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 05 Apr 2021 14:44:21 |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:57:13

[Name of Medication](#)

| Audit | User | Time (GMT) |
|---|--|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: CLOPIDOGREL - version WHODrug-Global-B3\\202003. | (b) (4) Coder Import (b) (4) | 05 Apr 2021 15:46:20 |
| 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 Apr 2021 15:46:20 |
| Data point term sent to Coder | System | 05 Apr 2021 14:45:45 |
| User entered 'Clopidogrel' | Brittany Belcher (b) (4) (b) (4) (b) (4) | 05 Apr 2021 14:45:03 |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:57:13

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered 'No (N)' | Brittany Belcher (b) (4) | 05 Apr 2021 14:45:03 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:57:13

[Indication](#)

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered 'Coronary Artery Disease (CAD)' | Brittany Belcher (b) (4) | 05 Apr 2021 14:45:03 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:57:13

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered '75' | Brittany Belcher (b) (4) | 05 Apr 2021 14:45:03 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:57:13

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered 'mg (mg)' | Brittany Belcher (b) (4) | 05 Apr 2021 14:45:03 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:57:13

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered empty. | Brittany Belcher (b) (4) | 05 Apr 2021 14:45:03 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:57:13

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered 'once daily (QD)' | Brittany Belcher (b) (4) | 05 Apr 2021 14:45:03 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:57:13

If frequency is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered empty. | Brittany Belcher (b) (4) | 05 Apr 2021 14:45:03 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:57:13

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered 'Oral (ORAL)' | Brittany Belcher (b) (4) | 05 Apr 2021 14:45:03 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:57:13

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered empty. | Brittany Belcher (b) (4) | 05 Apr 2021 14:45:03 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:57:13

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered '23 Feb 2021' | Brittany Belcher (b) (4) | 05 Apr 2021 14:45:03 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:57:13

Start date completely unknown

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered '0' | Brittany Belcher (b) (4) | 05 Apr 2021 14:45:03 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:57:13

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Brittany Belcher (b) (4) | 05 Apr 2021 14:45:03 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:57:13

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered empty. | Brittany Belcher (b) (4) | 05 Apr 2021 14:45:03 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:57:13

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered 'No (N)' | Brittany Belcher (b) (4) | 05 Apr 2021 14:45:03 |
| | | |
| | | |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:57:13

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 05 Apr 2021 14:45:03 |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:57:13

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 05 Apr 2021 14:45:03 |

US3302105

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:57:13

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 05 Apr 2021 14:45:03 |

US3302105

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 16:57:13

[Were any concomitant procedures performed?](#)

| Audit | User | Time (GMT) |
|--|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 05:15:55 |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| Signature has been broken. | (b) (4) Brittany Belcher (b) (4) | 05 Apr 2021 14:58:25 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | Brittany Belcher (b) (4) | 05 Apr 2021 14:58:25 |
| User signature succeeded. | Gregory Feldman (b) (4) | 19 Feb 2021 18:02:55 |
| User entered 'No (N)' | (b) (4) Brittany Belcher (b) (4) | 07 Aug 2020 20:39:18 |

US3302105

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:57:13

Procedure/Surgery date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered '20 Feb 2021' | Brittany Belcher (b) (4) | 05 Apr 2021 14:58:53 |
| | | |
| | | |

US3302105

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:57:13

[Procedure/Surgery](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered 'Heart Cath' | Brittany Belcher (b) (4) | 05 Apr 2021 14:58:53 |
| | | |
| | | |

US3302105

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:57:13

[Indication](#)

| Audit | User | Time (GMT) |
|---|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User closed query 'Indication is not Other, however specify has been provided. Please correct.' (Site from System). | System | 05 Apr 2021 14:59:10 |
| User entered 'Other (OTHER)' reason for change: Data Entry Error | Brittany Belcher (b) (4) | 05 Apr 2021 14:59:10 |
| | | |
| User opened query 'Indication is not Other, however specify has been provided. Please correct.' (Site from System). | System | 05 Apr 2021 14:58:53 |
| User entered 'Adverse Event (AE)' | Brittany Belcher (b) (4) | 05 Apr 2021 14:58:53 |
| | | |
| | | |

US3302105

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:57:13

If indication is Other, specify

| Audit | User | Time (GMT) |
|--|--------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| | (b) (4) | |
| User entered 'Myocardial Infarction (SAE)' | Brittany Belcher (b) (4) | 05 Apr 2021 14:58:53 |
| | | |
| | | |

US3302105

Folder: SAE USA-US087-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:57:13

[SAEID](#)

| Audit | User | Time (GMT) |
|---|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 31 Mar 2021 20:43:19 |
| User signature succeeded. | Gregory Feldman (b) (4) | 03 Mar 2021 18:51:48 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:18:43 |
| User entered 'USA-US087-2021-MRNA-1273-P301000020' | System | 22 Feb 2021 19:17:20 |

US3302105

Folder: SAE USA-US087-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:57:13

Serious

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 31 Mar 2021 20:43:19 |
| User signature succeeded. | Gregory Feldman (b) (4) | 03 Mar 2021 18:51:48 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:18:43 |
| User entered 'Yes (Y)' | System | 22 Feb 2021 19:17:20 |

US3302105

Folder: SAE USA-US087-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:57:13

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 31 Mar 2021 20:43:19 |
| User signature succeeded. | Gregory Feldman (b) (4) | 03 Mar 2021 18:51:48 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:18:43 |
| User entered 'No (N)' | System | 22 Feb 2021 19:17:20 |

US3302105

Folder: SAE USA-US087-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:57:13

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 31 Mar 2021 20:43:19 |
| User signature succeeded. | Gregory Feldman (b) (4) | 03 Mar 2021 18:51:48 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:18:43 |
| User entered 'No (N)' | System | 22 Feb 2021 19:17:20 |

US3302105

Folder: SAE USA-US087-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:57:13

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 31 Mar 2021 20:43:19 |
| User signature succeeded. | Gregory Feldman (b) (4) | 03 Mar 2021 18:51:48 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:18:43 |
| User entered 'Yes (Y)' | System | 22 Feb 2021 19:17:20 |

US3302105

Folder: SAE USA-US087-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:57:13

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 31 Mar 2021 20:43:19 |
| User signature succeeded. | Gregory Feldman (b) (4) | 03 Mar 2021 18:51:48 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:18:43 |
| User entered 'No (N)' | System | 22 Feb 2021 19:17:20 |

US3302105

Folder: SAE USA-US087-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:57:13

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 31 Mar 2021 20:43:19 |
| User signature succeeded. | Gregory Feldman (b) (4) | 03 Mar 2021 18:51:48 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:18:43 |
| User entered 'No (N)' | System | 22 Feb 2021 19:17:20 |

US3302105

Folder: SAE USA-US087-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:57:13

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 31 Mar 2021 20:43:19 |
| User signature succeeded. | Gregory Feldman (b) (4) | 03 Mar 2021 18:51:48 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:18:43 |
| User entered 'No (N)' | System | 22 Feb 2021 19:17:20 |

US3302105

Folder: SAE USA-US087-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:57:13

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 31 Mar 2021 20:43:19 |
| User signature succeeded. | Gregory Feldman (b) (4) | 03 Mar 2021 18:51:48 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:18:43 |
| User entered 'Gregory' | System | 22 Feb 2021 19:17:20 |

US3302105

Folder: SAE USA-US087-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:57:13

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 31 Mar 2021 20:43:19 |
| User signature succeeded. | Gregory Feldman (b) (4) | 03 Mar 2021 18:51:48 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:18:43 |
| User entered 'Feldman' | System | 22 Feb 2021 19:17:20 |

US3302105

Folder: SAE USA-US087-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:57:13

[Site Address: Street](#)

| Audit | User | Time (GMT) |
|---|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 31 Mar 2021 20:43:19 |
| User signature succeeded. | Gregory Feldman (b) (4) | 03 Mar 2021 18:51:48 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:18:43 |
| User entered '141 Harold Fleming Court' | System | 22 Feb 2021 19:17:20 |

US3302105

Folder: SAE USA-US087-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:57:13

[Site Address: City](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 31 Mar 2021 20:43:19 |
| User signature succeeded. | Gregory Feldman (b) (4) | 03 Mar 2021 18:51:48 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:18:43 |
| User entered 'Spartanburg' | System | 22 Feb 2021 19:17:20 |

US3302105

Folder: SAE USA-US087-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:57:13

[Site Address: Postal Code](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 31 Mar 2021 20:43:19 |
| User signature succeeded. | Gregory Feldman (b) (4) | 03 Mar 2021 18:51:48 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:18:43 |
| User entered '29303' | System | 22 Feb 2021 19:17:20 |

US3302105

Folder: SAE USA-US087-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:57:13

[Investigator Country](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 31 Mar 2021 20:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 08 Mar 2021 16:21:19 |
| User signature succeeded. | Gregory Feldman (b) (4) | 03 Mar 2021 18:51:48 |
| User entered 'US' | (b) (4) System | 22 Feb 2021 19:18:49 |

US3302105

Folder: SAE USA-US087-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:57:13

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '7' | System | 14 Apr 2021 12:46:02 |
| User entered '6' | System | 07 Apr 2021 13:07:29 |
| User entered '5' | System | 07 Apr 2021 12:52:07 |
| User entered '4' | System | 06 Apr 2021 14:50:54 |
| User entered '3' | System | 16 Mar 2021 15:28:30 |
| User entered '2' | System | 08 Mar 2021 16:21:58 |
| User entered '1' | System | 22 Feb 2021 19:18:49 |

US3302105

Folder: SAE USA-US087-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:57:13

[SAEID](#)

| Audit | User | Time (GMT) |
|---|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 31 Mar 2021 20:43:19 |
| User signature succeeded. | Gregory Feldman (b) (4) | 03 Mar 2021 18:51:48 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:18:43 |
| User entered 'USA-US087-2021-MRNA-1273-P301000020' | System | 22 Feb 2021 19:17:20 |

US3302105

Folder: SAE USA-US087-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:57:13

Serious

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 31 Mar 2021 20:43:19 |
| User signature succeeded. | Gregory Feldman (b) (4) | 03 Mar 2021 18:51:48 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:18:43 |
| User entered 'Yes (Y)' | System | 22 Feb 2021 19:17:20 |

US3302105

Folder: SAE USA-US087-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:57:13

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 31 Mar 2021 20:43:19 |
| User signature succeeded. | Gregory Feldman (b) (4) | 03 Mar 2021 18:51:48 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:18:43 |
| User entered 'No (N)' | System | 22 Feb 2021 19:17:20 |

US3302105

Folder: SAE USA-US087-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:57:13

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 31 Mar 2021 20:43:19 |
| User signature succeeded. | Gregory Feldman (b) (4) | 03 Mar 2021 18:51:48 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:18:43 |
| User entered 'No (N)' | System | 22 Feb 2021 19:17:20 |

US3302105

Folder: SAE USA-US087-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:57:13

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 31 Mar 2021 20:43:19 |
| User signature succeeded. | Gregory Feldman (b) (4) | 03 Mar 2021 18:51:48 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:18:43 |
| User entered 'Yes (Y)' | System | 22 Feb 2021 19:17:20 |

US3302105

Folder: SAE USA-US087-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:57:13

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 31 Mar 2021 20:43:19 |
| User signature succeeded. | Gregory Feldman (b) (4) | 03 Mar 2021 18:51:48 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:18:43 |
| User entered 'No (N)' | System | 22 Feb 2021 19:17:20 |

US3302105

Folder: SAE USA-US087-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:57:13

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 31 Mar 2021 20:43:19 |
| User signature succeeded. | Gregory Feldman (b) (4) | 03 Mar 2021 18:51:48 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:18:43 |
| User entered 'No (N)' | System | 22 Feb 2021 19:17:20 |

US3302105

Folder: SAE USA-US087-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:57:13

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 31 Mar 2021 20:43:19 |
| User signature succeeded. | Gregory Feldman (b) (4) | 03 Mar 2021 18:51:48 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:18:43 |
| User entered 'No (N)' | System | 22 Feb 2021 19:17:20 |

US3302105

Folder: SAE USA-US087-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:57:13

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 31 Mar 2021 20:43:19 |
| User signature succeeded. | Gregory Feldman (b) (4) | 03 Mar 2021 18:51:48 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:18:43 |
| User entered 'Gregory' | System | 22 Feb 2021 19:17:20 |

US3302105

Folder: SAE USA-US087-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:57:13

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 31 Mar 2021 20:43:19 |
| User signature succeeded. | Gregory Feldman (b) (4) | 03 Mar 2021 18:51:48 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:18:43 |
| User entered 'Feldman' | System | 22 Feb 2021 19:17:20 |

US3302105

Folder: SAE USA-US087-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:57:13

[Site Address: Street](#)

| Audit | User | Time (GMT) |
|---|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 31 Mar 2021 20:43:19 |
| User signature succeeded. | Gregory Feldman (b) (4) | 03 Mar 2021 18:51:48 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:18:43 |
| User entered '141 Harold Fleming Court' | System | 22 Feb 2021 19:17:20 |

US3302105

Folder: SAE USA-US087-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:57:13

[Site Address: City](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 31 Mar 2021 20:43:19 |
| User signature succeeded. | Gregory Feldman (b) (4) | 03 Mar 2021 18:51:48 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:18:43 |
| User entered 'Spartanburg' | System | 22 Feb 2021 19:17:20 |

US3302105

Folder: SAE USA-US087-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:57:13

[Site Address: Postal Code](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 31 Mar 2021 20:43:19 |
| User signature succeeded. | Gregory Feldman (b) (4) | 03 Mar 2021 18:51:48 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:18:43 |
| User entered '29303' | System | 22 Feb 2021 19:17:20 |

US3302105

Folder: SAE USA-US087-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:57:13

[Investigator Country](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 31 Mar 2021 20:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 08 Mar 2021 16:21:19 |
| User signature succeeded. | Gregory Feldman (b) (4) | 03 Mar 2021 18:51:48 |
| User entered 'US' | (b) (4) System | 22 Feb 2021 19:18:49 |

US3302105

Folder: SAE USA-US087-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:57:13

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '7' | System | 14 Apr 2021 12:46:02 |
| User entered '6' | System | 07 Apr 2021 13:07:29 |
| User entered '5' | System | 07 Apr 2021 12:52:07 |
| User entered '4' | System | 06 Apr 2021 14:50:54 |
| User entered '3' | System | 16 Mar 2021 15:28:30 |
| User entered '2' | System | 08 Mar 2021 16:21:58 |
| User entered '1' | System | 22 Feb 2021 19:18:49 |

US3302105

Folder: SAE USA-US087-2021-MRNA-1273-P301000020

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 16:57:13

[Date of submission \(Pre-filled from custom function\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 31 Mar 2021 20:43:19 |
| User signature succeeded. | Gregory Feldman (b) (4) | 03 Mar 2021 18:51:48 |
| User entered '22/Feb/2021 14:18' | (b) (4) System | 22 Feb 2021 19:18:49 |

US3302105

Folder: SAE USA-US087-2021-MRNA-1273-P301000020

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 16:57:13

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 31 Mar 2021 20:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 08 Mar 2021 16:21:19 |
| User signature succeeded. | Gregory Feldman (b) (4) | 03 Mar 2021 18:51:48 |
| User entered 'I' | (b) (4), (b) (6) | 22 Feb 2021 19:18:49 |

US3302105

Folder: SAE USA-US087-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:57:13

[SAEID](#)

| Audit | User | Time (GMT) |
|---|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 31 Mar 2021 20:43:19 |
| User signature succeeded. | Gregory Feldman (b) (4) | 03 Mar 2021 18:51:48 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:18:43 |
| User entered 'USA-US087-2021-MRNA-1273-P301000020' | System | 22 Feb 2021 19:17:20 |

US3302105

Folder: SAE USA-US087-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:57:13

Serious

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 31 Mar 2021 20:43:19 |
| User signature succeeded. | Gregory Feldman (b) (4) | 03 Mar 2021 18:51:48 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:18:43 |
| User entered 'Yes (Y)' | System | 22 Feb 2021 19:17:20 |

US3302105

Folder: SAE USA-US087-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:57:13

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 31 Mar 2021 20:43:19 |
| User signature succeeded. | Gregory Feldman (b) (4) | 03 Mar 2021 18:51:48 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:18:43 |
| User entered 'No (N)' | System | 22 Feb 2021 19:17:20 |

US3302105

Folder: SAE USA-US087-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:57:13

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 31 Mar 2021 20:43:19 |
| User signature succeeded. | Gregory Feldman (b) (4) | 03 Mar 2021 18:51:48 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:18:43 |
| User entered 'No (N)' | System | 22 Feb 2021 19:17:20 |

US3302105

Folder: SAE USA-US087-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:57:13

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 31 Mar 2021 20:43:19 |
| User signature succeeded. | Gregory Feldman (b) (4) | 03 Mar 2021 18:51:48 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:18:43 |
| User entered 'Yes (Y)' | System | 22 Feb 2021 19:17:20 |

US3302105

Folder: SAE USA-US087-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:57:13

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 31 Mar 2021 20:43:19 |
| User signature succeeded. | Gregory Feldman (b) (4) | 03 Mar 2021 18:51:48 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:18:43 |
| User entered 'No (N)' | System | 22 Feb 2021 19:17:20 |

US3302105

Folder: SAE USA-US087-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:57:13

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 31 Mar 2021 20:43:19 |
| User signature succeeded. | Gregory Feldman (b) (4) | 03 Mar 2021 18:51:48 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:18:43 |
| User entered 'No (N)' | System | 22 Feb 2021 19:17:20 |

US3302105

Folder: SAE USA-US087-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:57:13

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 31 Mar 2021 20:43:19 |
| User signature succeeded. | Gregory Feldman (b) (4) | 03 Mar 2021 18:51:48 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:18:43 |
| User entered 'No (N)' | System | 22 Feb 2021 19:17:20 |

US3302105

Folder: SAE USA-US087-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:57:13

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 31 Mar 2021 20:43:19 |
| User signature succeeded. | Gregory Feldman (b) (4) | 03 Mar 2021 18:51:48 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:18:43 |
| User entered 'Gregory' | System | 22 Feb 2021 19:17:20 |

US3302105

Folder: SAE USA-US087-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:57:13

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 31 Mar 2021 20:43:19 |
| User signature succeeded. | Gregory Feldman (b) (4) | 03 Mar 2021 18:51:48 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:18:43 |
| User entered 'Feldman' | System | 22 Feb 2021 19:17:20 |

US3302105

Folder: SAE USA-US087-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:57:13

[Site Address: Street](#)

| Audit | User | Time (GMT) |
|---|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 31 Mar 2021 20:43:19 |
| User signature succeeded. | Gregory Feldman (b) (4) | 03 Mar 2021 18:51:48 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:18:43 |
| User entered '141 Harold Fleming Court' | System | 22 Feb 2021 19:17:20 |

US3302105

Folder: SAE USA-US087-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:57:13

[Site Address: City](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 31 Mar 2021 20:43:19 |
| User signature succeeded. | Gregory Feldman (b) (4) | 03 Mar 2021 18:51:48 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:18:43 |
| User entered 'Spartanburg' | System | 22 Feb 2021 19:17:20 |

US3302105

Folder: SAE USA-US087-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:57:13

[Site Address: Postal Code](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 31 Mar 2021 20:43:19 |
| User signature succeeded. | Gregory Feldman (b) (4) | 03 Mar 2021 18:51:48 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:18:43 |
| User entered '29303' | System | 22 Feb 2021 19:17:20 |

US3302105

Folder: SAE USA-US087-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:57:13

[Investigator Country](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 31 Mar 2021 20:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 08 Mar 2021 16:21:19 |
| User signature succeeded. | Gregory Feldman (b) (4) | 03 Mar 2021 18:51:48 |
| User entered 'US' | (b) (4) System | 22 Feb 2021 19:18:49 |

US3302105

Folder: SAE USA-US087-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:57:13

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '7' | System | 14 Apr 2021 12:46:02 |
| User entered '6' | System | 07 Apr 2021 13:07:29 |
| User entered '5' | System | 07 Apr 2021 12:52:07 |
| User entered '4' | System | 06 Apr 2021 14:50:54 |
| User entered '3' | System | 16 Mar 2021 15:28:30 |
| User entered '2' | System | 08 Mar 2021 16:21:58 |
| User entered '1' | System | 22 Feb 2021 19:18:49 |

US3302105

Folder: SAE USA-US087-2021-MRNA-1273-P301000020

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 16:57:13

[Date of submission \(Pre-filled from custom function\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 31 Mar 2021 20:43:19 |
| User signature succeeded. | Gregory Feldman (b) (4) | 25 Mar 2021 18:02:56 |
| User entered '08/Mar/2021 16:21' | (b) (4) System | 08 Mar 2021 16:21:58 |

US3302105

Folder: SAE USA-US087-2021-MRNA-1273-P301000020

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 16:57:13

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 31 Mar 2021 20:43:19 |
| User signature succeeded. | Gregory Feldman (b) (4) | 25 Mar 2021 18:02:56 |
| Reviewed for Safety. | (b) (4), (b) (6) | 16 Mar 2021 15:28:15 |
| User entered 'I' | (b) (4), (b) (6) | 08 Mar 2021 16:21:58 |

US3302105

Folder: SAE USA-US087-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:57:13

[SAEID](#)

| Audit | User | Time (GMT) |
|---|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 31 Mar 2021 20:43:19 |
| User signature succeeded. | Gregory Feldman (b) (4) | 03 Mar 2021 18:51:48 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:18:43 |
| User entered 'USA-US087-2021-MRNA-1273-P301000020' | System | 22 Feb 2021 19:17:20 |

US3302105

Folder: SAE USA-US087-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:57:13

Serious

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 31 Mar 2021 20:43:19 |
| User signature succeeded. | Gregory Feldman (b) (4) | 03 Mar 2021 18:51:48 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:18:43 |
| User entered 'Yes (Y)' | System | 22 Feb 2021 19:17:20 |

US3302105

Folder: SAE USA-US087-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:57:13

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 31 Mar 2021 20:43:19 |
| User signature succeeded. | Gregory Feldman (b) (4) | 03 Mar 2021 18:51:48 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:18:43 |
| User entered 'No (N)' | System | 22 Feb 2021 19:17:20 |

US3302105

Folder: SAE USA-US087-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:57:13

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 31 Mar 2021 20:43:19 |
| User signature succeeded. | Gregory Feldman (b) (4) | 03 Mar 2021 18:51:48 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:18:43 |
| User entered 'No (N)' | System | 22 Feb 2021 19:17:20 |

US3302105

Folder: SAE USA-US087-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:57:13

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 31 Mar 2021 20:43:19 |
| User signature succeeded. | Gregory Feldman (b) (4) | 03 Mar 2021 18:51:48 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:18:43 |
| User entered 'Yes (Y)' | System | 22 Feb 2021 19:17:20 |

US3302105

Folder: SAE USA-US087-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:57:13

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 31 Mar 2021 20:43:19 |
| User signature succeeded. | Gregory Feldman (b) (4) | 03 Mar 2021 18:51:48 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:18:43 |
| User entered 'No (N)' | System | 22 Feb 2021 19:17:20 |

US3302105

Folder: SAE USA-US087-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:57:13

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 31 Mar 2021 20:43:19 |
| User signature succeeded. | Gregory Feldman (b) (4) | 03 Mar 2021 18:51:48 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:18:43 |
| User entered 'No (N)' | System | 22 Feb 2021 19:17:20 |

US3302105

Folder: SAE USA-US087-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:57:13

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 31 Mar 2021 20:43:19 |
| User signature succeeded. | Gregory Feldman (b) (4) | 03 Mar 2021 18:51:48 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:18:43 |
| User entered 'No (N)' | System | 22 Feb 2021 19:17:20 |

US3302105

Folder: SAE USA-US087-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:57:13

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 31 Mar 2021 20:43:19 |
| User signature succeeded. | Gregory Feldman (b) (4) | 03 Mar 2021 18:51:48 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:18:43 |
| User entered 'Gregory' | System | 22 Feb 2021 19:17:20 |

US3302105

Folder: SAE USA-US087-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:57:13

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 31 Mar 2021 20:43:19 |
| User signature succeeded. | Gregory Feldman (b) (4) | 03 Mar 2021 18:51:48 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:18:43 |
| User entered 'Feldman' | System | 22 Feb 2021 19:17:20 |

US3302105

Folder: SAE USA-US087-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:57:13

[Site Address: Street](#)

| Audit | User | Time (GMT) |
|---|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 31 Mar 2021 20:43:19 |
| User signature succeeded. | Gregory Feldman (b) (4) | 03 Mar 2021 18:51:48 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:18:43 |
| User entered '141 Harold Fleming Court' | System | 22 Feb 2021 19:17:20 |

US3302105

Folder: SAE USA-US087-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:57:13

[Site Address: City](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 31 Mar 2021 20:43:19 |
| User signature succeeded. | Gregory Feldman (b) (4) | 03 Mar 2021 18:51:48 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:18:43 |
| User entered 'Spartanburg' | System | 22 Feb 2021 19:17:20 |

US3302105

Folder: SAE USA-US087-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:57:13

[Site Address: Postal Code](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 31 Mar 2021 20:43:19 |
| User signature succeeded. | Gregory Feldman (b) (4) | 03 Mar 2021 18:51:48 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:18:43 |
| User entered '29303' | System | 22 Feb 2021 19:17:20 |

US3302105

Folder: SAE USA-US087-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:57:13

[Investigator Country](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 31 Mar 2021 20:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 08 Mar 2021 16:21:19 |
| User signature succeeded. | Gregory Feldman (b) (4) | 03 Mar 2021 18:51:48 |
| User entered 'US' | (b) (4) System | 22 Feb 2021 19:18:49 |

US3302105

Folder: SAE USA-US087-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:57:13

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '7' | System | 14 Apr 2021 12:46:02 |
| User entered '6' | System | 07 Apr 2021 13:07:29 |
| User entered '5' | System | 07 Apr 2021 12:52:07 |
| User entered '4' | System | 06 Apr 2021 14:50:54 |
| User entered '3' | System | 16 Mar 2021 15:28:30 |
| User entered '2' | System | 08 Mar 2021 16:21:58 |
| User entered '1' | System | 22 Feb 2021 19:18:49 |

US3302105

Folder: SAE USA-US087-2021-MRNA-1273-P301000020

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 16:57:13

[Date of submission \(Pre-filled from custom function\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 31 Mar 2021 20:43:19 |
| User signature succeeded. | Gregory Feldman (b) (4) | 25 Mar 2021 18:02:56 |
| User entered '16/Mar/2021 10:28' | (b) (4) System | 16 Mar 2021 15:28:30 |

US3302105

Folder: SAE USA-US087-2021-MRNA-1273-P301000020

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 16:57:13

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 06 Apr 2021 14:53:15 |
| DataPoint Verified. | (b) (4), (b) (6) | 31 Mar 2021 20:43:19 |
| User signature succeeded. | Gregory Feldman (b) (4) | 25 Mar 2021 18:02:56 |
| User entered 'I' | (b) (4), (b) (6) | 16 Mar 2021 15:28:30 |

US3302105

Folder: SAE USA-US087-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:57:13

[SAEID](#)

| Audit | User | Time (GMT) |
|---|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 31 Mar 2021 20:43:19 |
| User signature succeeded. | Gregory Feldman (b) (4) | 03 Mar 2021 18:51:48 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:18:43 |
| User entered 'USA-US087-2021-MRNA-1273-P301000020' | System | 22 Feb 2021 19:17:20 |

US3302105

Folder: SAE USA-US087-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:57:13

Serious

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 31 Mar 2021 20:43:19 |
| User signature succeeded. | Gregory Feldman (b) (4) | 03 Mar 2021 18:51:48 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:18:43 |
| User entered 'Yes (Y)' | System | 22 Feb 2021 19:17:20 |

US3302105

Folder: SAE USA-US087-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:57:13

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 31 Mar 2021 20:43:19 |
| User signature succeeded. | Gregory Feldman (b) (4) | 03 Mar 2021 18:51:48 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:18:43 |
| User entered 'No (N)' | System | 22 Feb 2021 19:17:20 |

US3302105

Folder: SAE USA-US087-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:57:13

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 31 Mar 2021 20:43:19 |
| User signature succeeded. | Gregory Feldman (b) (4) | 03 Mar 2021 18:51:48 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:18:43 |
| User entered 'No (N)' | System | 22 Feb 2021 19:17:20 |

US3302105

Folder: SAE USA-US087-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:57:13

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 31 Mar 2021 20:43:19 |
| User signature succeeded. | Gregory Feldman (b) (4) | 03 Mar 2021 18:51:48 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:18:43 |
| User entered 'Yes (Y)' | System | 22 Feb 2021 19:17:20 |

US3302105

Folder: SAE USA-US087-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:57:13

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 31 Mar 2021 20:43:19 |
| User signature succeeded. | Gregory Feldman (b) (4) | 03 Mar 2021 18:51:48 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:18:43 |
| User entered 'No (N)' | System | 22 Feb 2021 19:17:20 |

US3302105

Folder: SAE USA-US087-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:57:13

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 31 Mar 2021 20:43:19 |
| User signature succeeded. | Gregory Feldman (b) (4) | 03 Mar 2021 18:51:48 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:18:43 |
| User entered 'No (N)' | System | 22 Feb 2021 19:17:20 |

US3302105

Folder: SAE USA-US087-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:57:13

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 31 Mar 2021 20:43:19 |
| User signature succeeded. | Gregory Feldman (b) (4) | 03 Mar 2021 18:51:48 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:18:43 |
| User entered 'No (N)' | System | 22 Feb 2021 19:17:20 |

US3302105

Folder: SAE USA-US087-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:57:13

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 31 Mar 2021 20:43:19 |
| User signature succeeded. | Gregory Feldman (b) (4) | 03 Mar 2021 18:51:48 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:18:43 |
| User entered 'Gregory' | System | 22 Feb 2021 19:17:20 |

US3302105

Folder: SAE USA-US087-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:57:13

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 31 Mar 2021 20:43:19 |
| User signature succeeded. | Gregory Feldman (b) (4) | 03 Mar 2021 18:51:48 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:18:43 |
| User entered 'Feldman' | System | 22 Feb 2021 19:17:20 |

US3302105

Folder: SAE USA-US087-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:57:13

[Site Address: Street](#)

| Audit | User | Time (GMT) |
|---|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 31 Mar 2021 20:43:19 |
| User signature succeeded. | Gregory Feldman (b) (4) | 03 Mar 2021 18:51:48 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:18:43 |
| User entered '141 Harold Fleming Court' | System | 22 Feb 2021 19:17:20 |

US3302105

Folder: SAE USA-US087-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:57:13

[Site Address: City](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 31 Mar 2021 20:43:19 |
| User signature succeeded. | Gregory Feldman (b) (4) | 03 Mar 2021 18:51:48 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:18:43 |
| User entered 'Spartanburg' | System | 22 Feb 2021 19:17:20 |

US3302105

Folder: SAE USA-US087-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:57:13

[Site Address: Postal Code](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 31 Mar 2021 20:43:19 |
| User signature succeeded. | Gregory Feldman (b) (4) | 03 Mar 2021 18:51:48 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:18:43 |
| User entered '29303' | System | 22 Feb 2021 19:17:20 |

US3302105

Folder: SAE USA-US087-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:57:13

[Investigator Country](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 31 Mar 2021 20:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 08 Mar 2021 16:21:19 |
| User signature succeeded. | Gregory Feldman (b) (4) | 03 Mar 2021 18:51:48 |
| User entered 'US' | (b) (4) System | 22 Feb 2021 19:18:49 |

US3302105

Folder: SAE USA-US087-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:57:13

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '7' | System | 14 Apr 2021 12:46:02 |
| User entered '6' | System | 07 Apr 2021 13:07:29 |
| User entered '5' | System | 07 Apr 2021 12:52:07 |
| User entered '4' | System | 06 Apr 2021 14:50:54 |
| User entered '3' | System | 16 Mar 2021 15:28:30 |
| User entered '2' | System | 08 Mar 2021 16:21:58 |
| User entered '1' | System | 22 Feb 2021 19:18:49 |

US3302105

Folder: SAE USA-US087-2021-MRNA-1273-P301000020

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 16:57:13

[Date of submission \(Pre-filled from custom function\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|-------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| User entered '06/Apr/2021 10:50' | (b) (4) System | 06 Apr 2021 14:50:54 |

US3302105

Folder: SAE USA-US087-2021-MRNA-1273-P301000020

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 16:57:13

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| Reviewed for Safety. | (b) (4) | |
| | (b) (4), (b) (6) | 06 Apr 2021 14:53:15 |
| User entered 'I' | (b) (4), (b) (6) | 06 Apr 2021 14:50:54 |
| | | |

US3302105

Folder: SAE USA-US087-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:57:13

[SAEID](#)

| Audit | User | Time (GMT) |
|---|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 31 Mar 2021 20:43:19 |
| User signature succeeded. | Gregory Feldman (b) (4) | 03 Mar 2021 18:51:48 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:18:43 |
| User entered 'USA-US087-2021-MRNA-1273-P301000020' | System | 22 Feb 2021 19:17:20 |

US3302105

Folder: SAE USA-US087-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:57:13

Serious

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 31 Mar 2021 20:43:19 |
| User signature succeeded. | Gregory Feldman (b) (4) | 03 Mar 2021 18:51:48 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:18:43 |
| User entered 'Yes (Y)' | System | 22 Feb 2021 19:17:20 |

US3302105

Folder: SAE USA-US087-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:57:13

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 31 Mar 2021 20:43:19 |
| User signature succeeded. | Gregory Feldman (b) (4) | 03 Mar 2021 18:51:48 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:18:43 |
| User entered 'No (N)' | System | 22 Feb 2021 19:17:20 |

US3302105

Folder: SAE USA-US087-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:57:13

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 31 Mar 2021 20:43:19 |
| User signature succeeded. | Gregory Feldman (b) (4) | 03 Mar 2021 18:51:48 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:18:43 |
| User entered 'No (N)' | System | 22 Feb 2021 19:17:20 |

US3302105

Folder: SAE USA-US087-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:57:13

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 31 Mar 2021 20:43:19 |
| User signature succeeded. | Gregory Feldman (b) (4) | 03 Mar 2021 18:51:48 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:18:43 |
| User entered 'Yes (Y)' | System | 22 Feb 2021 19:17:20 |

US3302105

Folder: SAE USA-US087-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:57:13

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 31 Mar 2021 20:43:19 |
| User signature succeeded. | Gregory Feldman (b) (4) | 03 Mar 2021 18:51:48 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:18:43 |
| User entered 'No (N)' | System | 22 Feb 2021 19:17:20 |

US3302105

Folder: SAE USA-US087-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:57:13

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 31 Mar 2021 20:43:19 |
| User signature succeeded. | Gregory Feldman (b) (4) | 03 Mar 2021 18:51:48 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:18:43 |
| User entered 'No (N)' | System | 22 Feb 2021 19:17:20 |

US3302105

Folder: SAE USA-US087-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:57:13

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 31 Mar 2021 20:43:19 |
| User signature succeeded. | Gregory Feldman (b) (4) | 03 Mar 2021 18:51:48 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:18:43 |
| User entered 'No (N)' | System | 22 Feb 2021 19:17:20 |

US3302105

Folder: SAE USA-US087-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:57:13

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 31 Mar 2021 20:43:19 |
| User signature succeeded. | Gregory Feldman (b) (4) | 03 Mar 2021 18:51:48 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:18:43 |
| User entered 'Gregory' | System | 22 Feb 2021 19:17:20 |

US3302105

Folder: SAE USA-US087-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:57:13

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 31 Mar 2021 20:43:19 |
| User signature succeeded. | Gregory Feldman (b) (4) | 03 Mar 2021 18:51:48 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:18:43 |
| User entered 'Feldman' | System | 22 Feb 2021 19:17:20 |

US3302105

Folder: SAE USA-US087-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:57:13

[Site Address: Street](#)

| Audit | User | Time (GMT) |
|---|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 31 Mar 2021 20:43:19 |
| User signature succeeded. | Gregory Feldman (b) (4) | 03 Mar 2021 18:51:48 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:18:43 |
| User entered '141 Harold Fleming Court' | System | 22 Feb 2021 19:17:20 |

US3302105

Folder: SAE USA-US087-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:57:13

[Site Address: City](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 31 Mar 2021 20:43:19 |
| User signature succeeded. | Gregory Feldman (b) (4) | 03 Mar 2021 18:51:48 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:18:43 |
| User entered 'Spartanburg' | System | 22 Feb 2021 19:17:20 |

US3302105

Folder: SAE USA-US087-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:57:13

[Site Address: Postal Code](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 31 Mar 2021 20:43:19 |
| User signature succeeded. | Gregory Feldman (b) (4) | 03 Mar 2021 18:51:48 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:18:43 |
| User entered '29303' | System | 22 Feb 2021 19:17:20 |

US3302105

Folder: SAE USA-US087-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:57:13

[Investigator Country](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 31 Mar 2021 20:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 08 Mar 2021 16:21:19 |
| User signature succeeded. | Gregory Feldman (b) (4) | 03 Mar 2021 18:51:48 |
| User entered 'US' | (b) (4) System | 22 Feb 2021 19:18:49 |

US3302105

Folder: SAE USA-US087-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:57:13

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '7' | System | 14 Apr 2021 12:46:02 |
| User entered '6' | System | 07 Apr 2021 13:07:29 |
| User entered '5' | System | 07 Apr 2021 12:52:07 |
| User entered '4' | System | 06 Apr 2021 14:50:54 |
| User entered '3' | System | 16 Mar 2021 15:28:30 |
| User entered '2' | System | 08 Mar 2021 16:21:58 |
| User entered '1' | System | 22 Feb 2021 19:18:49 |

US3302105

Folder: SAE USA-US087-2021-MRNA-1273-P301000020

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 16:57:13

[Date of submission \(Pre-filled from custom function\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|-------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| User entered '07/Apr/2021 08:52' | (b) (4) System | 07 Apr 2021 12:52:07 |

US3302105

Folder: SAE USA-US087-2021-MRNA-1273-P301000020

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 16:57:13

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 14 Apr 2021 12:45:52 |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| User entered 'I' | (b) (4), (b) (6) | 07 Apr 2021 12:52:07 |

US3302105

Folder: SAE USA-US087-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:57:13

[SAEID](#)

| Audit | User | Time (GMT) |
|---|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 31 Mar 2021 20:43:19 |
| User signature succeeded. | Gregory Feldman (b) (4) | 03 Mar 2021 18:51:48 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:18:43 |
| User entered 'USA-US087-2021-MRNA-1273-P301000020' | System | 22 Feb 2021 19:17:20 |

US3302105

Folder: SAE USA-US087-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:57:13

Serious

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 31 Mar 2021 20:43:19 |
| User signature succeeded. | Gregory Feldman (b) (4) | 03 Mar 2021 18:51:48 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:18:43 |
| User entered 'Yes (Y)' | System | 22 Feb 2021 19:17:20 |

US3302105

Folder: SAE USA-US087-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:57:13

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 31 Mar 2021 20:43:19 |
| User signature succeeded. | Gregory Feldman (b) (4) | 03 Mar 2021 18:51:48 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:18:43 |
| User entered 'No (N)' | System | 22 Feb 2021 19:17:20 |

US3302105

Folder: SAE USA-US087-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:57:13

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 31 Mar 2021 20:43:19 |
| User signature succeeded. | Gregory Feldman (b) (4) | 03 Mar 2021 18:51:48 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:18:43 |
| User entered 'No (N)' | System | 22 Feb 2021 19:17:20 |

US3302105

Folder: SAE USA-US087-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:57:13

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 31 Mar 2021 20:43:19 |
| User signature succeeded. | Gregory Feldman (b) (4) | 03 Mar 2021 18:51:48 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:18:43 |
| User entered 'Yes (Y)' | System | 22 Feb 2021 19:17:20 |

US3302105

Folder: SAE USA-US087-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:57:13

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 31 Mar 2021 20:43:19 |
| User signature succeeded. | Gregory Feldman (b) (4) | 03 Mar 2021 18:51:48 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:18:43 |
| User entered 'No (N)' | System | 22 Feb 2021 19:17:20 |

US3302105

Folder: SAE USA-US087-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:57:13

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 31 Mar 2021 20:43:19 |
| User signature succeeded. | Gregory Feldman (b) (4) | 03 Mar 2021 18:51:48 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:18:43 |
| User entered 'No (N)' | System | 22 Feb 2021 19:17:20 |

US3302105

Folder: SAE USA-US087-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:57:13

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 31 Mar 2021 20:43:19 |
| User signature succeeded. | Gregory Feldman (b) (4) | 03 Mar 2021 18:51:48 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:18:43 |
| User entered 'No (N)' | System | 22 Feb 2021 19:17:20 |

US3302105

Folder: SAE USA-US087-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:57:13

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 31 Mar 2021 20:43:19 |
| User signature succeeded. | Gregory Feldman (b) (4) | 03 Mar 2021 18:51:48 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:18:43 |
| User entered 'Gregory' | System | 22 Feb 2021 19:17:20 |

US3302105

Folder: SAE USA-US087-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:57:13

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 31 Mar 2021 20:43:19 |
| User signature succeeded. | Gregory Feldman (b) (4) | 03 Mar 2021 18:51:48 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:18:43 |
| User entered 'Feldman' | System | 22 Feb 2021 19:17:20 |

US3302105

Folder: SAE USA-US087-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:57:13

[Site Address: Street](#)

| Audit | User | Time (GMT) |
|---|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 31 Mar 2021 20:43:19 |
| User signature succeeded. | Gregory Feldman (b) (4) | 03 Mar 2021 18:51:48 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:18:43 |
| User entered '141 Harold Fleming Court' | System | 22 Feb 2021 19:17:20 |

US3302105

Folder: SAE USA-US087-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:57:13

[Site Address: City](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 31 Mar 2021 20:43:19 |
| User signature succeeded. | Gregory Feldman (b) (4) | 03 Mar 2021 18:51:48 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:18:43 |
| User entered 'Spartanburg' | System | 22 Feb 2021 19:17:20 |

US3302105

Folder: SAE USA-US087-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:57:13

[Site Address: Postal Code](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 31 Mar 2021 20:43:19 |
| User signature succeeded. | Gregory Feldman (b) (4) | 03 Mar 2021 18:51:48 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:18:43 |
| User entered '29303' | System | 22 Feb 2021 19:17:20 |

US3302105

Folder: SAE USA-US087-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:57:13

[Investigator Country](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 31 Mar 2021 20:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 08 Mar 2021 16:21:19 |
| User signature succeeded. | Gregory Feldman (b) (4) | 03 Mar 2021 18:51:48 |
| User entered 'US' | (b) (4) System | 22 Feb 2021 19:18:49 |

US3302105

Folder: SAE USA-US087-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:57:13

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '7' | System | 14 Apr 2021 12:46:02 |
| User entered '6' | System | 07 Apr 2021 13:07:29 |
| User entered '5' | System | 07 Apr 2021 12:52:07 |
| User entered '4' | System | 06 Apr 2021 14:50:54 |
| User entered '3' | System | 16 Mar 2021 15:28:30 |
| User entered '2' | System | 08 Mar 2021 16:21:58 |
| User entered '1' | System | 22 Feb 2021 19:18:49 |

US3302105

Folder: SAE USA-US087-2021-MRNA-1273-P301000020

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 16:57:13

[Date of submission \(Pre-filled from custom function\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|-------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| User entered '07/Apr/2021 09:07' | (b) (4) System | 07 Apr 2021 13:07:29 |

US3302105

Folder: SAE USA-US087-2021-MRNA-1273-P301000020

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 16:57:13

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 14 Apr 2021 12:45:52 |
| User signature succeeded. | Gregory Feldman (b) (4) | 09 Apr 2021 12:37:50 |
| User entered 'I' | (b) (4), (b) (6) | 07 Apr 2021 13:07:29 |

US3302105

Folder: SAE USA-US087-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:57:13

[SAEID](#)

| Audit | User | Time (GMT) |
|---|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 31 Mar 2021 20:43:19 |
| User signature succeeded. | Gregory Feldman (b) (4) | 03 Mar 2021 18:51:48 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:18:43 |
| User entered 'USA-US087-2021-MRNA-1273-P301000020' | System | 22 Feb 2021 19:17:20 |

US3302105

Folder: SAE USA-US087-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:57:13

Serious

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 31 Mar 2021 20:43:19 |
| User signature succeeded. | Gregory Feldman (b) (4) | 03 Mar 2021 18:51:48 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:18:43 |
| User entered 'Yes (Y)' | System | 22 Feb 2021 19:17:20 |

US3302105

Folder: SAE USA-US087-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:57:13

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 31 Mar 2021 20:43:19 |
| User signature succeeded. | Gregory Feldman (b) (4) | 03 Mar 2021 18:51:48 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:18:43 |
| User entered 'No (N)' | System | 22 Feb 2021 19:17:20 |

US3302105

Folder: SAE USA-US087-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:57:13

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 31 Mar 2021 20:43:19 |
| User signature succeeded. | Gregory Feldman (b) (4) | 03 Mar 2021 18:51:48 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:18:43 |
| User entered 'No (N)' | System | 22 Feb 2021 19:17:20 |

US3302105

Folder: SAE USA-US087-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:57:13

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 31 Mar 2021 20:43:19 |
| User signature succeeded. | Gregory Feldman (b) (4) | 03 Mar 2021 18:51:48 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:18:43 |
| User entered 'Yes (Y)' | System | 22 Feb 2021 19:17:20 |

US3302105

Folder: SAE USA-US087-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:57:13

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 31 Mar 2021 20:43:19 |
| User signature succeeded. | Gregory Feldman (b) (4) | 03 Mar 2021 18:51:48 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:18:43 |
| User entered 'No (N)' | System | 22 Feb 2021 19:17:20 |

US3302105

Folder: SAE USA-US087-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:57:13

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 31 Mar 2021 20:43:19 |
| User signature succeeded. | Gregory Feldman (b) (4) | 03 Mar 2021 18:51:48 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:18:43 |
| User entered 'No (N)' | System | 22 Feb 2021 19:17:20 |

US3302105

Folder: SAE USA-US087-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:57:13

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 31 Mar 2021 20:43:19 |
| User signature succeeded. | Gregory Feldman (b) (4) | 03 Mar 2021 18:51:48 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:18:43 |
| User entered 'No (N)' | System | 22 Feb 2021 19:17:20 |

US3302105

Folder: SAE USA-US087-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:57:13

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 31 Mar 2021 20:43:19 |
| User signature succeeded. | Gregory Feldman (b) (4) | 03 Mar 2021 18:51:48 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:18:43 |
| User entered 'Gregory' | System | 22 Feb 2021 19:17:20 |

US3302105

Folder: SAE USA-US087-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:57:13

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 31 Mar 2021 20:43:19 |
| User signature succeeded. | Gregory Feldman (b) (4) | 03 Mar 2021 18:51:48 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:18:43 |
| User entered 'Feldman' | System | 22 Feb 2021 19:17:20 |

US3302105

Folder: SAE USA-US087-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:57:13

[Site Address: Street](#)

| Audit | User | Time (GMT) |
|---|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 31 Mar 2021 20:43:19 |
| User signature succeeded. | Gregory Feldman (b) (4) | 03 Mar 2021 18:51:48 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:18:43 |
| User entered '141 Harold Fleming Court' | System | 22 Feb 2021 19:17:20 |

US3302105

Folder: SAE USA-US087-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:57:13

[Site Address: City](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 31 Mar 2021 20:43:19 |
| User signature succeeded. | Gregory Feldman (b) (4) | 03 Mar 2021 18:51:48 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:18:43 |
| User entered 'Spartanburg' | System | 22 Feb 2021 19:17:20 |

US3302105

Folder: SAE USA-US087-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:57:13

[Site Address: Postal Code](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 31 Mar 2021 20:43:19 |
| User signature succeeded. | Gregory Feldman (b) (4) | 03 Mar 2021 18:51:48 |
| Reviewed for Safety. | (b) (4), (b) (6) | 22 Feb 2021 19:18:43 |
| User entered '29303' | System | 22 Feb 2021 19:17:20 |

US3302105

Folder: SAE USA-US087-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:57:13

[Investigator Country](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 31 Mar 2021 20:43:19 |
| Reviewed for Safety. | (b) (4), (b) (6) | 08 Mar 2021 16:21:19 |
| User signature succeeded. | Gregory Feldman (b) (4) | 03 Mar 2021 18:51:48 |
| User entered 'US' | (b) (4) System | 22 Feb 2021 19:18:49 |

US3302105

Folder: SAE USA-US087-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 16:57:13

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '7' | System | 14 Apr 2021 12:46:02 |
| User entered '6' | System | 07 Apr 2021 13:07:29 |
| User entered '5' | System | 07 Apr 2021 12:52:07 |
| User entered '4' | System | 06 Apr 2021 14:50:54 |
| User entered '3' | System | 16 Mar 2021 15:28:30 |
| User entered '2' | System | 08 Mar 2021 16:21:58 |
| User entered '1' | System | 22 Feb 2021 19:18:49 |

US3302105

Folder: SAE USA-US087-2021-MRNA-1273-P301000020

Form: Safety Report Form (7)

Generated On: 09 Jun 2021 16:57:13

[Date of submission \(Pre-filled from custom function\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|-------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| User entered '14/Apr/2021 07:46' | (b) (4) System | 14 Apr 2021 12:46:02 |

US3302105

Folder: SAE USA-US087-2021-MRNA-1273-P301000020

Form: Safety Report Form (7)

Generated On: 09 Jun 2021 16:57:13

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Gregory Feldman (b) (4) | 20 Apr 2021 17:48:52 |
| User entered 'I' | (b) (4) (b) (4), (b) (6) | 14 Apr 2021 12:46:02 |