

US3402284 (Prod: Meridian Clinical Research, LLC)

Generated By: KC Joubran

Generated On: 09 Jun 2021 17:25:19

All time stamps listed in this document are displayed in GMT

US3402284

Form: Participant Creation

Data signed: (b) (4) 26 Apr 2021 23:03:41

Generated On: 09 Jun 2021 17:25:19

[Participant ID](#)

US3402284

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

US3402284

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 17:46:50

Generated On: 09 Jun 2021 17:25:19

| | |
|---|---|
| Was this visit performed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Visit date (dd MMM yyyy) | 08 AUG 2020 |
| Was visit performed at the participant's home or at the clinic? | Home <input type="radio"/> |
| | Clinic <input checked="" type="radio"/> |
| Folder OID | SCRN |

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 15 Feb 2021 17:46:50

Generated On: 09 Jun 2021 17:25:19

| | |
|---|--|
| Date of Birth (MMM yyyy) | (b) (6) 1961 |
| Age | 58 |
| Age Units | YEARS |
| Age (Derived) | 59 |
| Sex | Female <input type="radio"/> Male <input checked="" type="radio"/> |
| Ethnicity | Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/> |
| Race (Check All That Apply) | |
| White | True |
| Black | False |
| Asian | False |
| American Indian or Alaska Native | False |
| Native Hawaiian or other Pacific Islander | False |
| Other | False |
| If race is Other, specify _____ | |
| Unknown | False |
| Not reported | False |

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 15 Feb 2021 17:46:50

Generated On: 09 Jun 2021 17:25:19

| | |
|---|--|
| Date of Informed Consent (<i>dd MMM yyyy</i>) | 08 AUG 2020 |
| Month and Year of Informed Consent (derived) | AUG 2020 |
| Year of Informed Consent (derived) | 2020 |
| Protocol Version | Amendment 1 <input type="radio"/> Amendment 2 <input checked="" type="radio"/> Amendment 3 <input type="radio"/> Amendment 4 <input type="radio"/> Amendment 5 <input type="radio"/> |
| Was participant enrolled in the study? | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| If No, indicate reason for screen fail | Withdrew Consent <input type="radio"/> Inclusion/Exclusion <input type="radio"/> Cohort Full <input type="radio"/> Other <input type="radio"/> |
| If reason for screen fail is Other, specify | |
| Was this participant screened previously? | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| If Yes, previous participant number | |
| Enrollment Trigger | 1 |

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 15 Feb 2021 17:46:50

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 15 Feb 2021 17:46:50

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Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 15 Feb 2021 17:46:50

Generated On: 09 Jun 2021 17:25:19

| | |
|---|--|
| Condition | DIABETES TYPE 2 |
| Start date (dd MMM yyyy) | UN UNK 2019 |
| Start date completely unknown | False |
| Condition ongoing at study entry | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| If No, please specify the stop date (dd MMM yyyy) _____ | |
| Stop date completely unknown | False |
| Start Month and Year (derived) | JAN 2019 |
| Start Year (derived) | 2019 |
| Stop Month and Year (derived) | _____ |
| Stop Year (derived) | _____ |

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 15 Feb 2021 17:46:50

Generated On: 09 Jun 2021 17:25:19

| | |
|---|--|
| Condition | CHOLECYSTECTOMY |
| Start date (dd MMM yyyy) | UN MAR 2019 |
| 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 MAR 2019 |
| Stop date completely unknown | False |
| Start Month and Year (derived) | MAR 2019 |
| Start Year (derived) | 2019 |
| Stop Month and Year (derived) | MAR 2019 |
| Stop Year (derived) | 2019 |

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 15 Feb 2021 17:46:50

Generated On: 09 Jun 2021 17:25:19

| | |
|---|--|
| Condition | OSTEOARTHRITIS LEFT HIP |
| Start date (dd MMM yyyy) | UN UNK 1982 |
| 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 1982 |
| Start Year (derived) | 1982 |
| Stop Month and Year (derived) | |
| Stop Year (derived) | |

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 15 Feb 2021 17:46:50

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| | |
|---|--|
| Condition | HYPERTENSION |
| 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) 15 Feb 2021 17:46:50

Generated On: 09 Jun 2021 17:25:19

| | |
|---|--|
| Condition | PINCHED NERVE LEFT SHOULDER |
| Start date (dd MMM yyyy) | UN FEB 2020 |
| 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) | FEB 2020 |
| Start Year (derived) | 2020 |
| Stop Month and Year (derived) | |
| Stop Year (derived) | |

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 15 Feb 2021 17:46:50

Generated On: 09 Jun 2021 17:25:19

| | |
|---|--|
| Condition | HYPERCHOLESTEROLEMIA |
| Start date (dd MMM yyyy) | UN MAY 2020 |
| 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) | MAY 2020 |
| Start Year (derived) | 2020 |
| Stop Month and Year (derived) | |
| Stop Year (derived) | |

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 15 Feb 2021 17:46:50

Generated On: 09 Jun 2021 17:25:19

| | |
|---|--|
| Condition | GOUT (RIGHT FOOT) |
| Start date (dd MMM yyyy) | UN UNK 2005 |
| Start date completely unknown | False |
| Condition ongoing at study entry | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| If No, please specify the stop date (dd MMM yyyy) | |
| Stop date completely unknown | False |
| Start Month and Year (derived) | JAN 2005 |
| Start Year (derived) | 2005 |
| Stop Month and Year (derived) | |
| Stop Year (derived) | |

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 15 Feb 2021 17:46:50

Generated On: 09 Jun 2021 17:25:19

| | |
|---|--|
| Condition | SLEEP APNEA |
| Start date (dd MMM yyyy) | UN UNK 2016 |
| 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 2016 |
| Start Year (derived) | 2016 |
| Stop Month and Year (derived) | |
| Stop Year (derived) | |

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 15 Feb 2021 17:46:50

Generated On: 09 Jun 2021 17:25:19

| | |
|---|--|
| Condition | PERTHES DISEASE |
| Start date (dd MMM yyyy) | UN UNK 2016 |
| 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 2016 |
| Start Year (derived) | 2016 |
| Stop Month and Year (derived) | |
| Stop Year (derived) | |

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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 15 Feb 2021 17:46:50

Generated On: 09 Jun 2021 17:25:19

| | |
|---|--|
| Condition | GALLSTONES |
| Start date (dd MMM yyyy) | UN UNK 2018 |
| 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 2019 |
| Stop date completely unknown | False |
| Start Month and Year (derived) | JAN 2018 |
| Start Year (derived) | 2018 |
| Stop Month and Year (derived) | JAN 2019 |
| Stop Year (derived) | 2019 |

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 17:46:50

Generated On: 09 Jun 2021 17:25:19

| | |
|-------------------------------------|--------------------------------------|
| Were vital signs assessed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Date of assessment (dd MMM yyyy) | 08 AUG 2020 |
| Time of assessment (00:00-23:59) | 07:58 (24 HR) |
| Vital Signs Date and Time (derived) | 08 AUG 2020 07:58 |
| Height (xxx.x) | 187.2 cm |
| Weight (xxx.x) | 139.8 kg |
| BMI (xxx.x) | 39.89289 kg/m ² |
| BMI units | KG/M2 |
| Temperature (xxx.x) | ND - Not Done |
| Route of measurement | Oral <input type="radio"/> |
| | Axillary <input type="radio"/> |
| | Other <input type="radio"/> |
| If Other, specify | |
| Pulse (xxx) | ND - Not Done |
| Pulse units | BPM |
| Respiratory Rate (xxx) | ND - Not Done |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | ND - Not Done |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | ND - Not Done |
| Diastolic Blood Pressure units | MMHG |
| Height (derived) | |
| Weight (derived) | |

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 17:46:50

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Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

08 AUG 2020

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 17:46:50

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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

CUSTODIAN (b) (6)

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 17:46:50

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 17:46:50

Generated On: 09 Jun 2021 17:25:19

| | |
|---|---|
| Was this visit performed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Visit date (dd MMM yyyy) | 08 AUG 2020 |
| Was visit performed at the participant's home or at the clinic? | Home <input type="radio"/> |
| | Clinic <input checked="" type="radio"/> |
| Folder OID | VISIT1 |

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 15 Feb 2021 17:46:50

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What was the date of randomization? (dd MMM yyyy) 08 AUG 2020

What was the participant's randomization number? 143108

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 15 Feb 2021 17:46:50

Generated On: 09 Jun 2021 17:25:19

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

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 17:46:50

Generated On: 09 Jun 2021 17:25:19

| | |
|-------------------------------------|--|
| 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) | 08 AUG 2020 |
| Time of assessment (00:00-23:59) | 07:58 (24 HR) |
| Vital Signs Date and Time (derived) | 08 AUG 2020 07:58 |
| Temperature (xxx.x) | 36.6 C |
| Route of measurement | Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/> |
| If Other, specify | |
| Pulse (xxx) | 81 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 15 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 138 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 82 mmHg |
| Diastolic Blood Pressure units | MMHG |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 17:46:50

Generated On: 09 Jun 2021 17:25:19

| | |
|-------------------------------------|---|
| Height | ND - Not Done |
| Weight | ND - Not Done |
| 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) | 08 AUG 2020 |
| Time of assessment (00:00-23:59) | 09:25 (24 HR) |
| Vital Signs Date and Time (derived) | 08 AUG 2020 09:25 |
| Temperature (xxx.x) | 36.6 C |
| Route of measurement | Oral <input checked="" type="checkbox"/> Axillary <input type="checkbox"/> Other <input type="checkbox"/> |
| If Other, specify | |
| Pulse (xxx) | 85 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 15 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 138 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 82 mmHg |
| Diastolic Blood Pressure units | MMHG |

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 17:46:50

Generated On: 09 Jun 2021 17:25:19

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

08 AUG 2020

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 17:46:50

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Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 08 AUG 2020

What was the treatment time? (00:00-23:59) 08:53 (24 HR)

Treatment Date and Time (derived) 08 AUG 2020 08:53

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 17:46:50

Generated On: 09 Jun 2021 17:25:19

| | |
|------------------------------------|--------------------------------------|
| Was the sample collected? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Collection date (dd MMM yyyy) | 08 AUG 2020 |
| Collection time (00:00-23:59) | 08:21 (24 HR) |
| Collection date and time (derived) | 08 AUG 2020 08:21 |

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 17:46:50

Generated On: 09 Jun 2021 17:25:19

| | | | |
|-------------------------------|---------------------------|---------------------------------|------------------------------------|
| Collection date (dd MMM yyyy) | | | 08 AUG 2020 |
| Lab Test | Was the sample collected? | Collection time (00:00 - 23:59) | Collection date and time (derived) |
| Nasopharyngeal Swab 1 | Yes | 08:10 | 08 AUG 2020 08:10 |
| Nasopharyngeal Swab 2 | No | | |

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:46:50

Generated On: 09 Jun 2021 17:25:19

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 17:25:19

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

97.9 °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 08 AUG 2020 09:18

PC Open Date & Time 08 AUG 2020 09:13

PC Close Date & Time 08 AUG 2020 11:43

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.4 °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 | 08 AUG 2020 17:10 |
| PC Open Date & Time | 08 AUG 2020 12:38 |
| PC Close Date & Time | 09 AUG 2020 11:59 |

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:25:19

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

98.0 °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 19:10

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3402284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

10 AUG 2020 18:58

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3402284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:25:19

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

97.6 °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

11 AUG 2020 17:12

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3402284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 AUG 2020 18:40

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3402284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °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

13 AUG 2020 19:48

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3402284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 AUG 2020 20:29

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3402284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:25:19

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

08 AUG 2020 09:17

PC Open Date & Time

08 AUG 2020 09:13

PC Close Date & Time

08 AUG 2020 11:43

US3402284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

08 AUG 2020 17:11

PC Open Date & Time

08 AUG 2020 12:38

PC Close Date & Time

09 AUG 2020 11:59

US3402284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:25:19

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

09 AUG 2020 19:10

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3402284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:25:19

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

10 AUG 2020 18:59

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3402284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:25:19

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

11 AUG 2020 17:13

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3402284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:25:19

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

12 AUG 2020 18:41

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3402284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:25:19

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

13 AUG 2020 19:49

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3402284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:25:19

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

14 AUG 2020 20:30

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:25:19

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 ☐

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:25:19

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

No ☒

Yes ☐

| | |
|----------------------|-------------------|
| PC Time stamp | 08 AUG 2020 09:16 |
| PC Open Date & Time | 08 AUG 2020 09:13 |
| PC Close Date & Time | 08 AUG 2020 11:43 |

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:25:19

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 ☐

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:25:19

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

No ☒

Yes ☐

| | |
|----------------------|-------------------|
| PC Time stamp | 08 AUG 2020 17:12 |
| PC Open Date & Time | 08 AUG 2020 12:38 |
| PC Close Date & Time | 09 AUG 2020 11:59 |

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:25:19

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 ☒

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:25:19

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 09 AUG 2020 19:11 |
| PC Open Date & Time | 09 AUG 2020 12:00 |
| PC Close Date & Time | 10 AUG 2020 11:59 |

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:25:19

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 10 AUG 2020 18:59 |
| PC Open Date & Time | 10 AUG 2020 12:00 |
| PC Close Date & Time | 11 AUG 2020 11:59 |

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

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US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:25:19

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

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:25:19

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 12 AUG 2020 18:41 |
| PC Open Date & Time | 12 AUG 2020 12:00 |
| PC Close Date & Time | 13 AUG 2020 11:59 |

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:25:19

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 ☒

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:25:19

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 13 AUG 2020 19:50 |
| PC Open Date & Time | 13 AUG 2020 12:00 |
| PC Close Date & Time | 14 AUG 2020 11:59 |

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:25:19

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 ☒

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Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:25:19

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 14 AUG 2020 20:31 |
| PC Open Date & Time | 14 AUG 2020 12:00 |
| PC Close Date & Time | 15 AUG 2020 11:59 |

US3402284

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp 15 AUG 2020 22:49

PC Open Date & Time 15 AUG 2020 12:00

PC Close Date & Time 16 AUG 2020 11:59

US3402284

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

16 AUG 2020 19:17

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3402284

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

DAY 10

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time Stamp

17 AUG 2020 17:47

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3402284

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(11)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

DAY 11

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

18 AUG 2020 21:09

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3402284

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(12)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

DAY 12

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

19 AUG 2020 18:52

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3402284

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(13)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

DAY 13

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

20 AUG 2020 18:42

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3402284

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(14)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

DAY 14

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time Stamp

21 AUG 2020 19:59

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3402284

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(15)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

DAY 15

Select one response below to indicate the intensity of your

None ☒

FATIGUE

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

22 AUG 2020 17:10

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3402284

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your **MUSCLE**

ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 15 AUG 2020 22:49

PC Open Date & Time 15 AUG 2020 12:00

PC Close Date & Time 16 AUG 2020 11:59

US3402284

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your **MUSCLE**

ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 16 AUG 2020 19:17

PC Open Date & Time 16 AUG 2020 12:00

PC Close Date & Time 17 AUG 2020 11:59

US3402284

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(10)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

DAY 10

Select one response below to indicate the intensity of your **MUSCLE**

ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time stamp 17 AUG 2020 17:48

PC Open Date & Time 17 AUG 2020 12:00

PC Close Date & Time 18 AUG 2020 11:59

US3402284

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(11)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

DAY 11

Select one response below to indicate the intensity of your **MUSCLE**

ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 18 AUG 2020 21:09

PC Open Date & Time 18 AUG 2020 12:00

PC Close Date & Time 19 AUG 2020 11:59

US3402284

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(12)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

DAY 12

Select one response below to indicate the intensity of your **MUSCLE**

ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 19 AUG 2020 18:52

PC Open Date & Time 19 AUG 2020 12:00

PC Close Date & Time 20 AUG 2020 11:59

US3402284

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(13)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

DAY 13

Select one response below to indicate the intensity of your **MUSCLE**
ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 20 AUG 2020 18:42

PC Open Date & Time 20 AUG 2020 12:00

PC Close Date & Time 21 AUG 2020 11:59

US3402284

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(14)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

DAY 14

Select one response below to indicate the intensity of your **MUSCLE**

ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time stamp 21 AUG 2020 20:00

PC Open Date & Time 21 AUG 2020 12:00

PC Close Date & Time 22 AUG 2020 11:59

US3402284

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(15)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

DAY 15

Select one response below to indicate the intensity of your **MUSCLE**

None ☒

ACHES ALL OVER BODY

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 22 AUG 2020 17:11

PC Open Date & Time 22 AUG 2020 12:00

PC Close Date & Time 23 AUG 2020 11:59

US3402284

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 15 AUG 2020 22:50

PC Open Date & Time 15 AUG 2020 12:00

PC Close Date & Time 16 AUG 2020 11:59

US3402284

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

PC Time stamp 16 AUG 2020 19:17

PC Open Date & Time 16 AUG 2020 12:00

PC Close Date & Time 17 AUG 2020 11:59

US3402284

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(10)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

DAY 10

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time stamp 17 AUG 2020 17:48

PC Open Date & Time 17 AUG 2020 12:00

PC Close Date & Time 18 AUG 2020 11:59

US3402284

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(11)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

DAY 11

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 18 AUG 2020 21:09

PC Open Date & Time 18 AUG 2020 12:00

PC Close Date & Time 19 AUG 2020 11:59

US3402284

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(12)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

DAY 12

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 19 AUG 2020 18:53

PC Open Date & Time 19 AUG 2020 12:00

PC Close Date & Time 20 AUG 2020 11:59

US3402284

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(13)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

DAY 13

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 20 AUG 2020 18:42

PC Open Date & Time 20 AUG 2020 12:00

PC Close Date & Time 21 AUG 2020 11:59

US3402284

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:25:19

| | |
|---|--|
| TIMEPOINT | DAY 8 |
| Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| PC Time stamp | 15 AUG 2020 22:50 |
| PC Open Date & Time | 15 AUG 2020 12:00 |
| PC Close Date & Time | 16 AUG 2020 11:59 |

US3402284

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 17:25:19

| | |
|---|--|
| TIMEPOINT | DAY 9 |
| Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| PC Time stamp | 16 AUG 2020 19:18 |
| PC Open Date & Time | 16 AUG 2020 12:00 |
| PC Close Date & Time | 17 AUG 2020 11:59 |

US3402284

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 17:25:19

| | |
|---|--|
| TIMEPOINT | DAY 10 |
| Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| PC Time stamp | 17 AUG 2020 17:48 |
| PC Open Date & Time | 17 AUG 2020 12:00 |
| PC Close Date & Time | 18 AUG 2020 11:59 |

US3402284

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 17:25:19

| | |
|---|--|
| TIMEPOINT | DAY 11 |
| Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| PC Time stamp | 18 AUG 2020 21:09 |
| PC Open Date & Time | 18 AUG 2020 12:00 |
| PC Close Date & Time | 19 AUG 2020 11:59 |

US3402284

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 09 Jun 2021 17:25:19

| | |
|---|--|
| TIMEPOINT | DAY 12 |
| Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| PC Time stamp | 19 AUG 2020 18:53 |
| PC Open Date & Time | 19 AUG 2020 12:00 |
| PC Close Date & Time | 20 AUG 2020 11:59 |

US3402284

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 09 Jun 2021 17:25:19

| | |
|---|--|
| TIMEPOINT | DAY 13 |
| Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| PC Time stamp | 20 AUG 2020 18:43 |
| PC Open Date & Time | 20 AUG 2020 12:00 |
| PC Close Date & Time | 21 AUG 2020 11:59 |

US3402284

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 09 Jun 2021 17:25:19

| | |
|---|--|
| TIMEPOINT | DAY 14 |
| Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| PC Time stamp | 21 AUG 2020 20:00 |
| PC Open Date & Time | 21 AUG 2020 12:00 |
| PC Close Date & Time | 22 AUG 2020 11:59 |

US3402284

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 09 Jun 2021 17:25:19

| | |
|---|--|
| TIMEPOINT | DAY 15 |
| Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| PC Time stamp | 22 AUG 2020 17:11 |
| PC Open Date & Time | 22 AUG 2020 12:00 |
| PC Close Date & Time | 23 AUG 2020 11:59 |

US3402284

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 17:46:50

Generated On: 09 Jun 2021 17:25:19

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 15 AUG 2020

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

Comments

If Contact Not Made, please provide Comments

US3402284

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:46:50

Generated On: 09 Jun 2021 17:25:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402284

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 17:46:50

Generated On: 09 Jun 2021 17:25:19

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3402284

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:46:50

Generated On: 09 Jun 2021 17:25:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402284

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 17:46:50

Generated On: 09 Jun 2021 17:25:19

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3402284

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:46:50

Generated On: 09 Jun 2021 17:25:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402284

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 17:46:50

Generated On: 09 Jun 2021 17:25:19

| | |
|---|---|
| Was this visit performed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Visit date (dd MMM yyyy) | 10 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 |

US3402284

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 17:46:50

Generated On: 09 Jun 2021 17:25:19

| | |
|-------------------------------------|---|
| 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) | 10 SEP 2020 |
| Time of assessment (00:00-23:59) | 15:36 (24 HR) |
| Vital Signs Date and Time (derived) | 10 SEP 2020 15:36 |
| Temperature (xxx.x) | 36.5 C |
| Route of measurement | Oral <input checked="" type="radio"/> |
| | Axillary <input type="radio"/> |
| | Other <input type="radio"/> |
| If Other, specify | |
| Pulse (xxx) | 91 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 15 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 138 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 87 mmHg |
| Diastolic Blood Pressure units | MMHG |

US3402284

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 17:46:50

Generated On: 09 Jun 2021 17:25:19

| | |
|-------------------------------------|---|
| 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) | 10 SEP 2020 |
| Time of assessment (00:00-23:59) | 16:50 (24 HR) |
| Vital Signs Date and Time (derived) | 10 SEP 2020 16:50 |
| Temperature (xxx.x) | 36.8 C |
| Route of measurement | Oral <input checked="" type="checkbox"/> |
| | Axillary <input type="checkbox"/> |
| | Other <input type="checkbox"/> |
| If Other, specify | |
| Pulse (xxx) | 87 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 15 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 126 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 80 mmHg |
| Diastolic Blood Pressure units | MMHG |

US3402284

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 17:46:50

Generated On: 09 Jun 2021 17:25:19

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

10 SEP 2020

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

US3402284

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 17:46:50

Generated On: 09 Jun 2021 17:25:19

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) 10 SEP 2020

What was the treatment time? (00:00-23:59) 16:17 (24 HR)

Treatment Date and Time (derived) 10 SEP 2020 16:17

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

US3402284

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 17:46:50

Generated On: 09 Jun 2021 17:25:19

| | |
|------------------------------------|--------------------------------------|
| Was the sample collected? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Collection date (dd MMM yyyy) | 10 SEP 2020 |
| Collection time (00:00-23:59) | 15:52 (24 HR) |
| Collection date and time (derived) | 10 SEP 2020 15:52 |

US3402284

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 17:46:50

Generated On: 09 Jun 2021 17:25:19

| | | | |
|-------------------------------|---------------------------|---------------------------------|------------------------------------|
| Collection date (dd MMM yyyy) | | | 10 SEP 2020 |
| Lab Test | Was the sample collected? | Collection time (00:00 - 23:59) | Collection date and time (derived) |
| Nasopharyngeal Swab 1 | Yes | 15:55 | 10 SEP 2020 15:55 |
| Nasopharyngeal Swab 2 | No | | |

US3402284

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:46:50

Generated On: 09 Jun 2021 17:25:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

10 SEP 2020 16:52

PC Open Date & Time

10 SEP 2020 16:37

PC Close Date & Time

10 SEP 2020 19:07

US3402284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.2 °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 | 10 SEP 2020 21:29 |
| PC Open Date & Time | 10 SEP 2020 20:02 |
| PC Close Date & Time | 11 SEP 2020 11:59 |

US3402284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °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

11 SEP 2020 19:53

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3402284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:25:19

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

98.7 °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

12 SEP 2020 19:07

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3402284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.8 °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

13 SEP 2020 20:32

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3402284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.4 °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):

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

To **PREVENT** pain or fever from occurring False

PC Time Stamp 14 SEP 2020 19:53

PC Open Date & Time 14 SEP 2020 12:00

PC Close Date & Time 15 SEP 2020 11:59

US3402284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °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):

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

15 SEP 2020 19:33

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3402284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 SEP 2020 20:04

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3402284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:25:19

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

10 SEP 2020 16:53

PC Open Date & Time

10 SEP 2020 16:37

PC Close Date & Time

10 SEP 2020 19:07

US3402284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

10 SEP 2020 21:30

PC Open Date & Time

10 SEP 2020 20:02

PC Close Date & Time

11 SEP 2020 11:59

US3402284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:25:19

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

11 SEP 2020 19:54

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3402284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:25:19

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

12 SEP 2020 19:08

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3402284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:25:19

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

13 SEP 2020 20:33

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3402284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:25:19

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

14 SEP 2020 19:53

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3402284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:25:19

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

15 SEP 2020 19:33

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3402284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:25:19

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

16 SEP 2020 20:04

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:25:19

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 ☐

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:25:19

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

No ☒

Yes ☐

| | |
|----------------------|-------------------|
| PC Time stamp | 10 SEP 2020 16:54 |
| PC Open Date & Time | 10 SEP 2020 16:37 |
| PC Close Date & Time | 10 SEP 2020 19:07 |

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:25:19

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 ☐

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:25:19

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

No ☒

Yes ☐

| | |
|----------------------|-------------------|
| PC Time stamp | 10 SEP 2020 21:31 |
| PC Open Date & Time | 10 SEP 2020 20:02 |
| PC Close Date & Time | 11 SEP 2020 11:59 |

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:25:19

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 ☒

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:25:19

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 11 SEP 2020 19:55 |
| PC Open Date & Time | 11 SEP 2020 12:00 |
| PC Close Date & Time | 12 SEP 2020 11:59 |

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:25:19

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 12 SEP 2020 19:08 |
| PC Open Date & Time | 12 SEP 2020 12:00 |
| PC Close Date & Time | 13 SEP 2020 11:59 |

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:25:19

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 13 SEP 2020 20:34 |
| PC Open Date & Time | 13 SEP 2020 12:00 |
| PC Close Date & Time | 14 SEP 2020 11:59 |

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:25:19

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 14 SEP 2020 19:54 |
| PC Open Date & Time | 14 SEP 2020 12:00 |
| PC Close Date & Time | 15 SEP 2020 11:59 |

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

DAY 6

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:25:19

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 15 SEP 2020 19:35 |
| PC Open Date & Time | 15 SEP 2020 12:00 |
| PC Close Date & Time | 16 SEP 2020 11:59 |

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:25:19

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 ☒

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:25:19

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 16 SEP 2020 20:05 |
| PC Open Date & Time | 16 SEP 2020 12:00 |
| PC Close Date & Time | 17 SEP 2020 11:59 |

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your **MUSCLE**

ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time stamp 17 SEP 2020 19:44

PC Open Date & Time 17 SEP 2020 12:00

PC Close Date & Time 18 SEP 2020 11:59

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(9)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your **MUSCLE**

ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time stamp 18 SEP 2020 20:53

PC Open Date & Time 18 SEP 2020 12:00

PC Close Date & Time 19 SEP 2020 11:59

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(10)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

DAY 10

Select one response below to indicate the intensity of your **MUSCLE**

ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp

19 SEP 2020 19:25

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(11)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

DAY 11

Select one response below to indicate the intensity of your **MUSCLE**

ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 21 SEP 2020 05:08

PC Open Date & Time 20 SEP 2020 12:00

PC Close Date & Time 21 SEP 2020 11:59

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(12)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

DAY 12

Select one response below to indicate the intensity of your **MUSCLE**

ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 21 SEP 2020 15:29

PC Open Date & Time 21 SEP 2020 12:00

PC Close Date & Time 22 SEP 2020 11:59

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(13)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

DAY 13

Select one response below to indicate the intensity of your **MUSCLE**

None ☐

ACHES ALL OVER BODY

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(14)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

DAY 14

Select one response below to indicate the intensity of your **MUSCLE**

ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 24 SEP 2020 08:18

PC Open Date & Time 23 SEP 2020 12:00

PC Close Date & Time 24 SEP 2020 11:59

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(15)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

DAY 15

Select one response below to indicate the intensity of your **MUSCLE**

ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 25 SEP 2020 11:40

PC Open Date & Time 24 SEP 2020 12:00

PC Close Date & Time 25 SEP 2020 11:59

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(16)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

DAY 16

Select one response below to indicate the intensity of your **MUSCLE**

ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 26 SEP 2020 00:00

PC Open Date & Time 25 SEP 2020 12:00

PC Close Date & Time 26 SEP 2020 11:59

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(17)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

DAY 17

Select one response below to indicate the intensity of your **MUSCLE**

ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 26 SEP 2020 17:12

PC Open Date & Time 26 SEP 2020 12:00

PC Close Date & Time 27 SEP 2020 11:59

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(18)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

DAY 18

Select one response below to indicate the intensity of your **MUSCLE**

ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 27 SEP 2020 19:12

PC Open Date & Time 27 SEP 2020 12:00

PC Close Date & Time 28 SEP 2020 11:59

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(19)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

DAY 19

Select one response below to indicate the intensity of your **MUSCLE**

None ☐

ACHES ALL OVER BODY

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(20)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

DAY 20

Select one response below to indicate the intensity of your **MUSCLE**

ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp

29 SEP 2020 15:32

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(21)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

DAY 21

Select one response below to indicate the intensity of your **MUSCLE**

None ☐

ACHES ALL OVER BODY

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(22)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

DAY 22

Select one response below to indicate the intensity of your **MUSCLE**

ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 01 OCT 2020 20:31

PC Open Date & Time 01 OCT 2020 12:00

PC Close Date & Time 02 OCT 2020 11:59

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(23)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

DAY 23

Select one response below to indicate the intensity of your **MUSCLE**

ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 02 OCT 2020 20:26

PC Open Date & Time 02 OCT 2020 12:00

PC Close Date & Time 03 OCT 2020 11:59

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(24)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

DAY 24

Select one response below to indicate the intensity of your **MUSCLE**

None ☒

ACHES ALL OVER BODY

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 03 OCT 2020 20:47

PC Open Date & Time 03 OCT 2020 12:00

PC Close Date & Time 04 OCT 2020 11:59

US3402284

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(8)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 17 SEP 2020 19:44

PC Open Date & Time 17 SEP 2020 12:00

PC Close Date & Time 18 SEP 2020 11:59

US3402284

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(9)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

PC Time stamp 18 SEP 2020 20:53

PC Open Date & Time 18 SEP 2020 12:00

PC Close Date & Time 19 SEP 2020 11:59

US3402284

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(10)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

DAY 10

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 19 SEP 2020 19:25

PC Open Date & Time 19 SEP 2020 12:00

PC Close Date & Time 20 SEP 2020 11:59

US3402284

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(11)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

DAY 11

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 21 SEP 2020 05:08

PC Open Date & Time 20 SEP 2020 12:00

PC Close Date & Time 21 SEP 2020 11:59

US3402284

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(12)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

DAY 12

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 21 SEP 2020 15:28

PC Open Date & Time 21 SEP 2020 12:00

PC Close Date & Time 22 SEP 2020 11:59

US3402284

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(13)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

DAY 13

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3402284

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(14)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

DAY 14

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 24 SEP 2020 08:19

PC Open Date & Time 23 SEP 2020 12:00

PC Close Date & Time 24 SEP 2020 11:59

US3402284

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(15)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

DAY 15

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 25 SEP 2020 11:40

PC Open Date & Time 24 SEP 2020 12:00

PC Close Date & Time 25 SEP 2020 11:59

US3402284

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(16)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

DAY 16

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 26 SEP 2020 00:00

PC Open Date & Time 25 SEP 2020 12:00

PC Close Date & Time 26 SEP 2020 11:59

US3402284

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(17)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

DAY 17

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 26 SEP 2020 17:11

PC Open Date & Time 26 SEP 2020 12:00

PC Close Date & Time 27 SEP 2020 11:59

US3402284

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(18)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

DAY 18

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 27 SEP 2020 19:12

PC Open Date & Time 27 SEP 2020 12:00

PC Close Date & Time 28 SEP 2020 11:59

US3402284

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(19)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

DAY 19

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3402284

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(20)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

DAY 20

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 29 SEP 2020 15:32

PC Open Date & Time 29 SEP 2020 12:00

PC Close Date & Time 30 SEP 2020 11:59

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:25:19

| | |
|---|--|
| TIMEPOINT | DAY 8 |
| Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| PC Time stamp | 17 SEP 2020 19:45 |
| PC Open Date & Time | 17 SEP 2020 12:00 |
| PC Close Date & Time | 18 SEP 2020 11:59 |

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 17:25:19

| | |
|---|--|
| TIMEPOINT | DAY 9 |
| Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| PC Time stamp | 18 SEP 2020 20:53 |
| PC Open Date & Time | 18 SEP 2020 12:00 |
| PC Close Date & Time | 19 SEP 2020 11:59 |

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 17:25:19

| | |
|---|--|
| TIMEPOINT | DAY 10 |
| Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| PC Time stamp | 19 SEP 2020 19:25 |
| PC Open Date & Time | 19 SEP 2020 12:00 |
| PC Close Date & Time | 20 SEP 2020 11:59 |

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 17:25:19

| | |
|---|--|
| TIMEPOINT | DAY 11 |
| Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| PC Time stamp | 21 SEP 2020 05:07 |
| PC Open Date & Time | 20 SEP 2020 12:00 |
| PC Close Date & Time | 21 SEP 2020 11:59 |

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(12)

Generated On: 09 Jun 2021 17:25:19

| | |
|---|--|
| TIMEPOINT | DAY 12 |
| Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| PC Time stamp | 21 SEP 2020 15:28 |
| PC Open Date & Time | 21 SEP 2020 12:00 |
| PC Close Date & Time | 22 SEP 2020 11:59 |

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(13)

Generated On: 09 Jun 2021 17:25:19

| | |
|---|------------------------------|
| TIMEPOINT | DAY 13 |
| Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms? | No <input type="checkbox"/> |
| | Yes <input type="checkbox"/> |
| PC Time stamp | |
| PC Open Date & Time | 22 SEP 2020 12:00 |
| PC Close Date & Time | 23 SEP 2020 11:59 |

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(14)

Generated On: 09 Jun 2021 17:25:19

| | |
|---|--|
| TIMEPOINT | DAY 14 |
| Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms? | No <input type="radio"/> Yes <input checked="" type="radio"/> |
| PC Time stamp | 24 SEP 2020 08:19 |
| PC Open Date & Time | 23 SEP 2020 12:00 |
| PC Close Date & Time | 24 SEP 2020 11:59 |

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(15)

Generated On: 09 Jun 2021 17:25:19

| | |
|---|--|
| TIMEPOINT | DAY 15 |
| Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| PC Time stamp | 25 SEP 2020 11:39 |
| PC Open Date & Time | 24 SEP 2020 12:00 |
| PC Close Date & Time | 25 SEP 2020 11:59 |

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(16)

Generated On: 09 Jun 2021 17:25:19

| | |
|---|--|
| TIMEPOINT | DAY 16 |
| Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| PC Time stamp | 26 SEP 2020 00:00 |
| PC Open Date & Time | 25 SEP 2020 12:00 |
| PC Close Date & Time | 26 SEP 2020 11:59 |

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(17)

Generated On: 09 Jun 2021 17:25:19

| | |
|---|--|
| TIMEPOINT | DAY 17 |
| Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| PC Time stamp | 26 SEP 2020 17:11 |
| PC Open Date & Time | 26 SEP 2020 12:00 |
| PC Close Date & Time | 27 SEP 2020 11:59 |

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(18)

Generated On: 09 Jun 2021 17:25:19

| | |
|---|--|
| TIMEPOINT | DAY 18 |
| Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| PC Time stamp | 27 SEP 2020 19:12 |
| PC Open Date & Time | 27 SEP 2020 12:00 |
| PC Close Date & Time | 28 SEP 2020 11:59 |

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(19)

Generated On: 09 Jun 2021 17:25:19

| | |
|---|------------------------------|
| TIMEPOINT | DAY 19 |
| Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms? | No <input type="checkbox"/> |
| | Yes <input type="checkbox"/> |
| PC Time stamp | |
| PC Open Date & Time | 28 SEP 2020 12:00 |
| PC Close Date & Time | 29 SEP 2020 11:59 |

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(20)

Generated On: 09 Jun 2021 17:25:19

| | |
|---|--|
| TIMEPOINT | DAY 20 |
| Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| PC Time stamp | 29 SEP 2020 15:31 |
| PC Open Date & Time | 29 SEP 2020 12:00 |
| PC Close Date & Time | 30 SEP 2020 11:59 |

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(21)

Generated On: 09 Jun 2021 17:25:19

| | |
|---|------------------------------|
| TIMEPOINT | DAY 21 |
| Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms? | No <input type="checkbox"/> |
| | Yes <input type="checkbox"/> |
| PC Time stamp | |
| PC Open Date & Time | 30 SEP 2020 12:00 |
| PC Close Date & Time | 01 OCT 2020 11:59 |

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(22)

Generated On: 09 Jun 2021 17:25:19

| | |
|---|--|
| TIMEPOINT | DAY 22 |
| Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| PC Time stamp | 01 OCT 2020 20:31 |
| PC Open Date & Time | 01 OCT 2020 12:00 |
| PC Close Date & Time | 02 OCT 2020 11:59 |

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(23)

Generated On: 09 Jun 2021 17:25:19

| | |
|---|--|
| TIMEPOINT | DAY 23 |
| Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| PC Time stamp | 02 OCT 2020 20:26 |
| PC Open Date & Time | 02 OCT 2020 12:00 |
| PC Close Date & Time | 03 OCT 2020 11:59 |

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(24)

Generated On: 09 Jun 2021 17:25:19

| | |
|---|--|
| TIMEPOINT | DAY 24 |
| Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| PC Time stamp | 03 OCT 2020 20:47 |
| PC Open Date & Time | 03 OCT 2020 12:00 |
| PC Close Date & Time | 04 OCT 2020 11:59 |

US3402284

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 17:46:50

Generated On: 09 Jun 2021 17:25:19

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

17 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3402284

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:46:50

Generated On: 09 Jun 2021 17:25:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402284

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 17:46:50

Generated On: 09 Jun 2021 17:25:19

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

24 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3402284

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:46:50

Generated On: 09 Jun 2021 17:25:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402284

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 17:46:50

Generated On: 09 Jun 2021 17:25:19

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

02 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3402284

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:46:50

Generated On: 09 Jun 2021 17:25:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402284

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 17:46:50

Generated On: 09 Jun 2021 17:25:19

| | |
|---|---|
| Was this visit performed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Visit date (dd MMM yyyy) | 08 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 |

US3402284

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 17:46:50

Generated On: 09 Jun 2021 17:25:19

| | |
|---|---------------------------------------|
| Were vital signs assessed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Date of assessment (<i>dd MMM yyyy</i>) | 08 OCT 2020 |
| Time of assessment (<i>00:00-23:59</i>) | 15:04 (24 HR) |
| Vital Signs Date and Time (derived) | 08 OCT 2020 15:04 |
| Temperature (<i>xxx.x</i>) | 98.7 F |
| Route of measurement | Oral <input checked="" type="radio"/> |
| | Axillary <input type="radio"/> |
| | Other <input type="radio"/> |
| If Other, specify | |
| Pulse (<i>xxx</i>) | 88 beats/min |
| Pulse units | BPM |
| Respiratory Rate (<i>xxx</i>) | 14 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (<i>xxx</i>) | 122 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (<i>xxx</i>) | 80 mmHg |
| Diastolic Blood Pressure units | MMHG |
| Height (derived) | |
| Weight (derived) | |

US3402284

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 17:46:50

Generated On: 09 Jun 2021 17:25:19

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.

US3402284

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 17:46:50

Generated On: 09 Jun 2021 17:25:19

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

08 OCT 2020

Collection time (00:00-23:59)

15:17 (24 HR)

Collection date and time (derived)

08 OCT 2020 15:17

US3402284

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:46:50

Generated On: 09 Jun 2021 17:25:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402284

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

| TIMEPOINT | DAY 64 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input checked="" type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input checked="" type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input 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 | 08 OCT 2020 14:28:34 |
| Patient Cloud Open Date & Time | 08 OCT 2020 00:01 |
| Patient Cloud Close Date & Time | 12 OCT 2020 23:59 |

US3402284

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

| 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 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 | 15 OCT 2020 10:29:38 |
| Patient Cloud Open Date & Time | 15 OCT 2020 00:01 |
| Patient Cloud Close Date & Time | 19 OCT 2020 23:59 |

US3402284

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

| 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 | 22 OCT 2020 20:21:55 |
| Patient Cloud Open Date & Time | 22 OCT 2020 00:01 |
| Patient Cloud Close Date & Time | 26 OCT 2020 23:59 |

US3402284

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

| 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 | 05 NOV 2020 15:45:33 |
| Patient Cloud Open Date & Time | 05 NOV 2020 00:01 |
| Patient Cloud Close Date & Time | 09 NOV 2020 23:59 |

US3402284

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

DAY 99

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

12 NOV 2020 10:33:30

Patient Cloud Open Date & Time

12 NOV 2020 00:01

Patient Cloud Close Date & Time

16 NOV 2020 23:59

US3402284

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

| 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"/> |

US3402284

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

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

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

Date and time of submission

Patient Cloud Open Date & Time

19 NOV 2020 00:01

Patient Cloud Close Date & Time

23 NOV 2020 23:59

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

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 16:48:31

Patient Cloud Open Date & Time

16 NOV 2020 00:01

Patient Cloud Close Date & Time

20 NOV 2020 23:59

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

| TIMEPOINT | DAY 110 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Date and time of submission | 26 NOV 2020 11:14:40 |
| Patient Cloud Open Date & Time | 23 NOV 2020 00:01 |
| Patient Cloud Close Date & Time | 27 NOV 2020 23:59 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

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

02 DEC 2020 21:35:47

Patient Cloud Open Date & Time

30 NOV 2020 00:01

Patient Cloud Close Date & Time

04 DEC 2020 23:59

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

| 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 19:03:56 |
| Patient Cloud Open Date & Time | 07 DEC 2020 00:01 |
| Patient Cloud Close Date & Time | 11 DEC 2020 23:59 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

16 DEC 2020 18:22:50

Patient Cloud Open Date & Time

14 DEC 2020 00:01

Patient Cloud Close Date & Time

18 DEC 2020 23:59

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

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

24 DEC 2020 22:09:05

Patient Cloud Open Date & Time

21 DEC 2020 00:01

Patient Cloud Close Date & Time

25 DEC 2020 23:59

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

| TIMEPOINT | DAY 145 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Date and time of submission | 31 DEC 2020 12:38:27 |
| Patient Cloud Open Date & Time | 28 DEC 2020 00:01 |
| Patient Cloud Close Date & Time | 01 JAN 2021 23:59 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

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 20:13:47

Patient Cloud Open Date & Time

04 JAN 2021 00:01

Patient Cloud Close Date & Time

08 JAN 2021 23:59

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

| TIMEPOINT | DAY 159 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input checked="" type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input checked="" type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input checked="" type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature \geq 100.4°F/38°C) | False |
| Chills | False |
| Cough | False |
| Shortness of breath | False |
| Difficulty breathing | False |
| Fatigue | False |
| Muscle aches | True |
| Body aches | True |
| Headache | False |
| New loss of taste | False |
| New loss of smell | False |
| Sore throat | False |
| Congestion | False |
| Runny nose | True |
| Nausea | False |
| Vomiting | False |
| Diarrhea | False |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input checked="" type="radio"/> |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

Please contact your study clinic immediately. Click below to confirm that you have read this 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 | 11 JAN 2021 08:50:23 |
| Patient Cloud Open Date & Time | 11 JAN 2021 00:01 |
| Patient Cloud Close Date & Time | 15 JAN 2021 23:59 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

| 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 type="radio"/> Yes <input checked="" type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input 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 | 19 JAN 2021 09:38:50 |
| Patient Cloud Open Date & Time | 18 JAN 2021 00:01 |
| Patient Cloud Close Date & Time | 22 JAN 2021 23:59 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

29 JAN 2021 06:36:49

Patient Cloud Open Date & Time

25 JAN 2021 00:01

Patient Cloud Close Date & Time

29 JAN 2021 23:59

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

| 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 | 02 FEB 2021 17:19:18 |
| Patient Cloud Open Date & Time | 01 FEB 2021 00:01 |
| Patient Cloud Close Date & Time | 05 FEB 2021 23:59 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

| TIMEPOINT | DAY 187 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Date and time of submission | 08 FEB 2021 18:37:46 |
| Patient Cloud Open Date & Time | 08 FEB 2021 00:01 |
| Patient Cloud Close Date & Time | 12 FEB 2021 23:59 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

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

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

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

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 FEB 2021 20:57:38

Patient Cloud Open Date & Time

22 FEB 2021 00:01

Patient Cloud Close Date & Time

26 FEB 2021 23:59

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 MAR 2021 15:51:13

Patient Cloud Open Date & Time

01 MAR 2021 00:01

Patient Cloud Close Date & Time

05 MAR 2021 23:59

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

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

08 MAR 2021 18:23:39

Patient Cloud Open Date & Time

08 MAR 2021 00:01

Patient Cloud Close Date & Time

12 MAR 2021 23:59

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

19 MAR 2021 05:18:33

Patient Cloud Open Date & Time

15 MAR 2021 00:01

Patient Cloud Close Date & Time

19 MAR 2021 23:59

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

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 19:56:01

Patient Cloud Open Date & Time

22 MAR 2021 00:01

Patient Cloud Close Date & Time

26 MAR 2021 23:59

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

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

31 MAR 2021 16:17:10

Patient Cloud Open Date & Time

29 MAR 2021 00:01

Patient Cloud Close Date & Time

02 APR 2021 23:59

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

08 APR 2021 20:01:41

Patient Cloud Open Date & Time

05 APR 2021 00:01

Patient Cloud Close Date & Time

09 APR 2021 23:59

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

DAY 250

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

13 APR 2021 21:06:55

Patient Cloud Open Date & Time

12 APR 2021 00:01

Patient Cloud Close Date & Time

16 APR 2021 23:59

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

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

21 APR 2021 17:57:46

Patient Cloud Open Date & Time

19 APR 2021 00:01

Patient Cloud Close Date & Time

23 APR 2021 23:59

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

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 18:40:52

Patient Cloud Open Date & Time

26 APR 2021 00:01

Patient Cloud Close Date & Time

30 APR 2021 23:59

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

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

03 MAY 2021 16:06:51

Patient Cloud Open Date & Time

03 MAY 2021 00:01

Patient Cloud Close Date & Time

07 MAY 2021 23:59

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

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 ☐

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

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

[Patient Cloud Close Date & Time](#)

14 MAY 2021 23:59

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

| 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"/> |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

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

[Patient Cloud Close Date & Time](#)

21 MAY 2021 23:59

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

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 ☐

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

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

[Patient Cloud Close Date & Time](#)

28 MAY 2021 23:59

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

| 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"/> |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

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

[Patient Cloud Close Date & Time](#)

04 JUN 2021 23:59

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

DAY 306

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

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

[Patient Cloud Close Date & Time](#)

11 JUN 2021 23:59

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

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 ☐

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

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

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

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

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

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

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

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 ☐

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

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

[Patient Cloud Close Date & Time](#)

02 JUL 2021 23:59

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

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

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

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

[Patient Cloud Close Date & Time](#)

09 JUL 2021 23:59

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

| 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"/> |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

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

[Patient Cloud Close Date & Time](#)

16 JUL 2021 23:59

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

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

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

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

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

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 ☐

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

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

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

DAY 362

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

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

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

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

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

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

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

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

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

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

[Patient Cloud Close Date & Time](#)

06 AUG 2021 23:59

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

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 ☐

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

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

[Patient Cloud Close Date & Time](#)

13 AUG 2021 23:59

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

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 ☐

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

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

| | |
|---|-------------------|
| Patient Cloud Close Date & Time | 20 AUG 2021 23:59 |
|---|-------------------|

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

DAY 383

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

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

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

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

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

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

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

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

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 AUG 2021 00:01 |
| Patient Cloud Close Date & Time | 27 AUG 2021 23:59 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

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 ☐ 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 ☐

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

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

[Patient Cloud Close Date & Time](#)

03 SEP 2021 23:59

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

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 ☐

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

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

[Patient Cloud Close Date & Time](#)

10 SEP 2021 23:59

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

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

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

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

[Patient Cloud Close Date & Time](#)

17 SEP 2021 23:59

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

| 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"/> |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 SEP 2021 00:01 |
| Patient Cloud Close Date & Time | 24 SEP 2021 23:59 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

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 ☐ 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 ☐

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

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

[Patient Cloud Close Date & Time](#)

01 OCT 2021 23:59

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

DAY 425

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

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

[Patient Cloud Close Date & Time](#)

08 OCT 2021 23:59

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

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 ☐

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 OCT 2021 00:01 |
| Patient Cloud Close Date & Time | 15 OCT 2021 23:59 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

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 ☐ 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 ☐

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

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

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

| 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"/> |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

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

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

DAY 453

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

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

[Patient Cloud Close Date & Time](#)

05 NOV 2021 23:59

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

| 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"/> |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

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

[Patient Cloud Close Date & Time](#)

12 NOV 2021 23:59

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

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

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

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

[Patient Cloud Close Date & Time](#)

19 NOV 2021 23:59

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

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 ☐

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 2021 00:01 |
| Patient Cloud Close Date & Time | 26 NOV 2021 23:59 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

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 ☐ 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 ☐

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 NOV 2021 00:01 |
| Patient Cloud Close Date & Time | 03 DEC 2021 23:59 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

| 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"/> |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

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

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

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

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

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

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

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 ☐

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 DEC 2021 00:01 |
| Patient Cloud Close Date & Time | 24 DEC 2021 23:59 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

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 ☐

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 DEC 2021 00:01 |
| Patient Cloud Close Date & Time | 31 DEC 2021 23:59 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

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 ☐

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

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

[Patient Cloud Close Date & Time](#)

07 JAN 2022 23:59

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

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 ☐

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

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

[Patient Cloud Close Date & Time](#)

14 JAN 2022 23:59

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

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

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JAN 2022 00:01 |
| Patient Cloud Close Date & Time | 21 JAN 2022 23:59 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

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 ☐

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JAN 2022 00:01 |
| Patient Cloud Close Date & Time | 28 JAN 2022 23:59 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

DAY 544

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

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

[Patient Cloud Close Date & Time](#)

04 FEB 2022 23:59

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

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 ☐

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

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

[Patient Cloud Close Date & Time](#)

11 FEB 2022 23:59

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

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 ☐

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

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

[Patient Cloud Close Date & Time](#)

18 FEB 2022 23:59

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

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°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 ☐

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
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|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 21 FEB 2022 00:01 |
| Patient Cloud Close Date & Time | 25 FEB 2022 23:59 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

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 ☐

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

04 MAR 2022 23:59

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

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 ☐

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

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

[Patient Cloud Open Date & Time](#)

07 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

11 MAR 2022 23:59

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

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 ☐

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

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

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

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 ☐

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

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

[Patient Cloud Close Date & Time](#)

25 MAR 2022 23:59

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

| 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="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"/> |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

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

[Patient Cloud Close Date & Time](#)

01 APR 2022 23:59

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

| 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="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"/> |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

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

[Patient Cloud Close Date & Time](#)

08 APR 2022 23:59

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

| TIMEPOINT | DAY 614 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

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

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

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

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

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

[Patient Cloud Close Date & Time](#)

22 APR 2022 23:59

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

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

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

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

[Patient Cloud Close Date & Time](#)

29 APR 2022 23:59

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

| 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="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"/> |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

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

[Patient Cloud Close Date & Time](#)

06 MAY 2022 23:59

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

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 ☐

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

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

[Patient Cloud Close Date & Time](#)

13 MAY 2022 23:59

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

DAY 649

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

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

[Patient Cloud Close Date & Time](#)

20 MAY 2022 23:59

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

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 ☐

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

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

[Patient Cloud Close Date & Time](#)

27 MAY 2022 23:59

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

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 ☐

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

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

[Patient Cloud Close Date & Time](#)

03 JUN 2022 23:59

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

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

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

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

[Patient Cloud Close Date & Time](#)

10 JUN 2022 23:59

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

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 ☐

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JUN 2022 00:01 |
| Patient Cloud Close Date & Time | 17 JUN 2022 23:59 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

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

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

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

[Patient Cloud Close Date & Time](#)

24 JUN 2022 23:59

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

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

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

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

[Patient Cloud Close Date & Time](#)

01 JUL 2022 23:59

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

| 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"/> |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

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

[Patient Cloud Close Date & Time](#)

08 JUL 2022 23:59

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

| 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="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"/> |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

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

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

DAY 712

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 2022 00:01 |
| Patient Cloud Close Date & Time | 22 JUL 2022 23:59 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

| TIMEPOINT | DAY 719 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

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

[Patient Cloud Close Date & Time](#)

29 JUL 2022 23:59

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

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 ☐ 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 ☐

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

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

[Patient Cloud Close Date & Time](#)

05 AUG 2022 23:59

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

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

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

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

[Patient Cloud Close Date & Time](#)

12 AUG 2022 23:59

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

| 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"/> |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

19 AUG 2022 23:59

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

| 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"/> |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 2022 00:01 |
| Patient Cloud Close Date & Time | 26 AUG 2022 23:59 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

| 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"/> |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

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

[Patient Cloud Close Date & Time](#)

02 SEP 2022 23:59

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

| 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"/> |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

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

[Patient Cloud Close Date & Time](#)

09 SEP 2022 23:59

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

| 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"/> |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

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

[Patient Cloud Close Date & Time](#)

16 SEP 2022 23:59

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

DAY 775

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

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

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

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

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

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

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

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

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

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

[Patient Cloud Close Date & Time](#)

23 SEP 2022 23:59

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

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 ☐

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 2022 00:01 |
| Patient Cloud Close Date & Time | 30 SEP 2022 23:59 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

DAY 789

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

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

[Patient Cloud Close Date & Time](#)

07 OCT 2022 23:59

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

| 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"/> |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 2022 00:01 |
| Patient Cloud Close Date & Time | 14 OCT 2022 23:59 |

US3402284

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 17:25:19

| 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 15:50:51 |

US3402284

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 08 Mar 2021 22:24:41

Generated On: 09 Jun 2021 17:25:19

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

03 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3402284

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 08 Mar 2021 22:24:41

Generated On: 09 Jun 2021 17:25:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402284

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 26 Apr 2021 23:03:42

Generated On: 09 Jun 2021 17:25:19

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

7 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3402284

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 23:03:42

Generated On: 09 Jun 2021 17:25:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402284

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 26 Apr 2021 23:04:13

Generated On: 09 Jun 2021 17:25:19

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

6 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3402284

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 23:03:42

Generated On: 09 Jun 2021 17:25:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402284

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 26 Apr 2021 23:04:13

Generated On: 09 Jun 2021 17:25:19

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

8 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3402284

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 23:04:13

Generated On: 09 Jun 2021 17:25:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402284

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 26 Apr 2021 23:04:13

Generated On: 09 Jun 2021 17:25:19

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

| | |
|--------------------------|-------------|
| Visit date (dd MMM yyyy) | 09 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 |
|------------|--------|

US3402284

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 26 Apr 2021 23:04:13

Generated On: 09 Jun 2021 17:25:19

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

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

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3402284

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Apr 2021 23:04:13

Generated On: 09 Jun 2021 17:25:19

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.

US3402284

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Apr 2021 23:04:13

Generated On: 09 Jun 2021 17:25:19

| | |
|------------------------------------|--------------------------------------|
| Was the sample collected? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Collection date (dd MMM yyyy) | 09 MAR 2021 |
| Collection time (00:00-23:59) | 11:33 (24 HR) |
| Collection date and time (derived) | 09 MAR 2021 11:33 |

US3402284

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 23:04:13

Generated On: 09 Jun 2021 17:25:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402284

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 26 Apr 2021 23:04:13

Generated On: 09 Jun 2021 17:25:19

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

6 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3402284

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 23:04:13

Generated On: 09 Jun 2021 17:25:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402284

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:25:19

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

US3402284

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:25:19

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: COVID-19 Contact

Data signed: (b) (4) 26 Apr 2021 23:03:42

Generated On: 09 Jun 2021 17:25:19

| | |
|--|--|
| Date of Contact | 12 JAN 2021 |
| Time of Contact | 19:00 |
| Date and Time of Contact (derived) | 12 JAN 2021 19:00 |
| Type of Contact | <div>Clinic Visit - Scheduled <input checked="" type="radio"/></div> <div>Clinical Visit - Unscheduled <input type="radio"/></div> <div>Safety Call <input type="radio"/></div> <div>Convalescent Tele-visit <input type="radio"/></div> |
| Has the subject reported symptoms of SARS-COV-2? | <div>Yes <input checked="" type="radio"/></div> <div>No <input type="radio"/></div> |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (1)

Data signed: (b) (4) 26 Apr 2021 23:03:42

Generated On: 09 Jun 2021 17:25:19

Symptom Day

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

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (1)

Data signed: (b) (4) 26 Apr 2021 23:03:42

Generated On: 09 Jun 2021 17:25:19

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

| | |
|------|-------------|
| Date | 10 JAN 2021 |
|------|-------------|

| | |
|---------------------|------|
| Assessment Not Done | True |
|---------------------|------|

| | |
|---------------|----------------------|
| O2 Saturation | <input type="text"/> |
|---------------|----------------------|

| | |
|---------------------|----------------------|
| O2 Saturation Units | <input type="text"/> |
|---------------------|----------------------|

| | |
|-------------|----------------------|
| Temperature | <input type="text"/> |
|-------------|----------------------|

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

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

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

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

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EAB) (1725)

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Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (1)

Data signed: (b) (4) 26 Apr 2021 23:03:42

Generated On: 09 Jun 2021 17:25:19

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

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (1)

Data signed: (b) (4) 26 Apr 2021 23:03:42

Generated On: 09 Jun 2021 17:25:19

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

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (2)

Data signed: (b) (4) 26 Apr 2021 23:03:42

Generated On: 09 Jun 2021 17:25:19

Symptom Day

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

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Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (2)

Data signed: (b) (4) 26 Apr 2021 23:03:42

Generated On: 09 Jun 2021 17:25:19

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

| | |
|------|-------------|
| Date | 11 JAN 2021 |
|------|-------------|

| | |
|---------------------|------|
| Assessment Not Done | True |
|---------------------|------|

| | |
|---------------|----------------------|
| O2 Saturation | <input type="text"/> |
|---------------|----------------------|

| | |
|---------------------|----------------------|
| O2 Saturation Units | <input type="text"/> |
|---------------------|----------------------|

| | |
|-------------|----------------------|
| Temperature | <input type="text"/> |
|-------------|----------------------|

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

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

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

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (2)

Data signed: (b) (4) 26 Apr 2021 23:03:42

Generated On: 09 Jun 2021 17:25:19

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

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Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (2)

Data signed: (b) (4) 26 Apr 2021 23:03:42

Generated On: 09 Jun 2021 17:25:19

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

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (3)

Data signed: (b) (4) 26 Apr 2021 23:03:42

Generated On: 09 Jun 2021 17:25:19

Symptom Day

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

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (3)

Data signed: (b) (4) 26 Apr 2021 23:03:42

Generated On: 09 Jun 2021 17:25:19

| | | |
|-----------------------------|-------------|----------------------------------|
| | Day 33 | <input type="checkbox"/> |
| | Day 34 | <input type="checkbox"/> |
| | Day 35 | <input type="checkbox"/> |
| | Day 36 | <input type="checkbox"/> |
| | Day 37 | <input type="checkbox"/> |
| | Day 38 | <input type="checkbox"/> |
| | Day 39 | <input type="checkbox"/> |
| | Day 40 | <input type="checkbox"/> |
| Date | 12 JAN 2021 | |
| Assessment Not Done | False | |
| O2 Saturation | 98 % | |
| O2 Saturation Units | % | |
| Temperature | 36.5 C | |
| Chills | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Cough | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Shortness of Breath | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Difficulty Breathing | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| PRODUCTION RELEASE (v12.003 | | 409 of 3231 |
| EAB) (1725) | | |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (3)

Data signed: (b) (4) 26 Apr 2021 23:03:42

Generated On: 09 Jun 2021 17:25:19

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

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (3)

Data signed: (b) (4) 26 Apr 2021 23:03:42

Generated On: 09 Jun 2021 17:25:19

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

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Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (4)

Data signed: (b) (4) 26 Apr 2021 23:03:42

Generated On: 09 Jun 2021 17:25:19

Symptom Day

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

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Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (4)

Data signed: (b) (4) 26 Apr 2021 23:03:42

Generated On: 09 Jun 2021 17:25:19

| | | |
|-----------------------------|-------------|----------------------------------|
| | Day 33 | <input type="checkbox"/> |
| | Day 34 | <input type="checkbox"/> |
| | Day 35 | <input type="checkbox"/> |
| | Day 36 | <input type="checkbox"/> |
| | Day 37 | <input type="checkbox"/> |
| | Day 38 | <input type="checkbox"/> |
| | Day 39 | <input type="checkbox"/> |
| | Day 40 | <input type="checkbox"/> |
| Date | 13 JAN 2021 | |
| Assessment Not Done | False | |
| O2 Saturation | 99 % | |
| O2 Saturation Units | % | |
| Temperature | 97.4 F | |
| Chills | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Cough | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Shortness of Breath | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Difficulty Breathing | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| PRODUCTION RELEASE (v12.003 | | 413 of 3231 |
| EAB) (1725) | | |

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Form: Symptom Log (4)

Data signed: (b) (4) 26 Apr 2021 23:03:42

Generated On: 09 Jun 2021 17:25:19

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

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Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (4)

Data signed: (b) (4) 26 Apr 2021 23:03:42

Generated On: 09 Jun 2021 17:25:19

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

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Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (5)

Data signed: (b) (4) 26 Apr 2021 23:03:42

Generated On: 09 Jun 2021 17:25:19

Symptom Day

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

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Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (5)

Data signed: (b) (4) 26 Apr 2021 23:03:42

Generated On: 09 Jun 2021 17:25:19

| | | |
|-----------------------------|-------------|----------------------------------|
| | Day 33 | <input type="checkbox"/> |
| | Day 34 | <input type="checkbox"/> |
| | Day 35 | <input type="checkbox"/> |
| | Day 36 | <input type="checkbox"/> |
| | Day 37 | <input type="checkbox"/> |
| | Day 38 | <input type="checkbox"/> |
| | Day 39 | <input type="checkbox"/> |
| | Day 40 | <input type="checkbox"/> |
| Date | 14 JAN 2021 | |
| Assessment Not Done | False | |
| O2 Saturation | 98 % | |
| O2 Saturation Units | % | |
| Temperature | 97.8 F | |
| Chills | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Cough | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Shortness of Breath | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Difficulty Breathing | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| PRODUCTION RELEASE (v12.003 | | 417 of 3231 |
| EAB) (1725) | | |

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Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (5)

Data signed: (b) (4) 26 Apr 2021 23:03:42

Generated On: 09 Jun 2021 17:25:19

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

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Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (5)

Data signed: (b) (4) 26 Apr 2021 23:03:42

Generated On: 09 Jun 2021 17:25:19

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

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Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (6)

Data signed: (b) (4) 26 Apr 2021 23:03:42

Generated On: 09 Jun 2021 17:25:19

Symptom Day

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

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Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (6)

Data signed: (b) (4) 26 Apr 2021 23:03:42

Generated On: 09 Jun 2021 17:25:19

| | | |
|-----------------------------|-------------|----------------------------------|
| | Day 33 | <input type="checkbox"/> |
| | Day 34 | <input type="checkbox"/> |
| | Day 35 | <input type="checkbox"/> |
| | Day 36 | <input type="checkbox"/> |
| | Day 37 | <input type="checkbox"/> |
| | Day 38 | <input type="checkbox"/> |
| | Day 39 | <input type="checkbox"/> |
| | Day 40 | <input type="checkbox"/> |
| Date | 15 JAN 2021 | |
| Assessment Not Done | False | |
| O2 Saturation | 99 % | |
| O2 Saturation Units | % | |
| Temperature | 96.1 F | |
| Chills | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Cough | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Shortness of Breath | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Difficulty Breathing | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| PRODUCTION RELEASE (v12.003 | | 421 of 3231 |
| EAB) (1725) | | |

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Form: Symptom Log (6)

Data signed: (b) (4) 26 Apr 2021 23:03:42

Generated On: 09 Jun 2021 17:25:19

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

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Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (6)

Data signed: (b) (4) 26 Apr 2021 23:03:42

Generated On: 09 Jun 2021 17:25:19

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

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Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (7)

Data signed: (b) (4) 26 Apr 2021 23:03:42

Generated On: 09 Jun 2021 17:25:19

Symptom Day

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

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Form: Symptom Log (7)

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

| | |
|------|-------------|
| Date | 16 JAN 2021 |
|------|-------------|

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

| | |
|---------------|------|
| O2 Saturation | 97 % |
|---------------|------|

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

| | |
|-------------|--------|
| Temperature | 96.0 F |
|-------------|--------|

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

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

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

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

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

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Form: Symptom Log (7)

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

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Form: Symptom Log (8)

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Symptom Day

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

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Form: Symptom Log (8)

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| | | |
|-----------------------------|-------------|----------------------------------|
| | Day 33 | <input type="checkbox"/> |
| | Day 34 | <input type="checkbox"/> |
| | Day 35 | <input type="checkbox"/> |
| | Day 36 | <input type="checkbox"/> |
| | Day 37 | <input type="checkbox"/> |
| | Day 38 | <input type="checkbox"/> |
| | Day 39 | <input type="checkbox"/> |
| | Day 40 | <input type="checkbox"/> |
| Date | 17 JAN 2021 | |
| Assessment Not Done | False | |
| O2 Saturation | 97 % | |
| O2 Saturation Units | % | |
| Temperature | 96.7 F | |
| Chills | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Cough | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Shortness of Breath | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Difficulty Breathing | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
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| | | |
|------------------------|----------|----------------------------------|
| | Not Done | <input type="radio"/> |
| Fatigue | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Muscle Aches (Myalgia) | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Body Aches | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Headache | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| New Loss of Taste | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| New Loss of Smell | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |

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Form: Symptom Log (8)

Data signed: (b) (4) 26 Apr 2021 23:03:42

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

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Form: Symptom Log (9)

Data signed: (b) (4) 26 Apr 2021 23:03:42

Generated On: 09 Jun 2021 17:25:19

Symptom Day

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

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Form: Symptom Log (9)

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

| | |
|------|-------------|
| Date | 18 JAN 2021 |
|------|-------------|

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

| | |
|---------------|------|
| O2 Saturation | 97 % |
|---------------|------|

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

| | |
|-------------|--------|
| Temperature | 98.2 F |
|-------------|--------|

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

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

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

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

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

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Form: Symptom Log (9)

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Generated On: 09 Jun 2021 17:25:19

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

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Form: Symptom Log (10)

Data signed: (b) (4) 26 Apr 2021 23:03:42

Generated On: 09 Jun 2021 17:25:19

Symptom Day

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

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Form: Symptom Log (10)

Data signed: (b) (4) 26 Apr 2021 23:03:42

Generated On: 09 Jun 2021 17:25:19

| | | |
|--|-------------|----------------------------------|
| | Day 33 | <input type="checkbox"/> |
| | Day 34 | <input type="checkbox"/> |
| | Day 35 | <input type="checkbox"/> |
| | Day 36 | <input type="checkbox"/> |
| | Day 37 | <input type="checkbox"/> |
| | Day 38 | <input type="checkbox"/> |
| | Day 39 | <input type="checkbox"/> |
| | Day 40 | <input type="checkbox"/> |
| Date | 19 JAN 2021 | |
| Assessment Not Done | False | |
| O2 Saturation | 99 % | |
| O2 Saturation Units | % | |
| Temperature | 96.2 F | |
| Chills | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Cough | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Shortness of Breath | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Difficulty Breathing | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
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| | | |
|------------------------|----------|----------------------------------|
| | Not Done | <input type="radio"/> |
| Fatigue | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Muscle Aches (Myalgia) | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Body Aches | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Headache | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| New Loss of Taste | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| New Loss of Smell | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |

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Form: Symptom Log (10)

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

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Form: Symptom Log (11)

Data signed: (b) (4) 26 Apr 2021 23:03:42

Generated On: 09 Jun 2021 17:25:19

Symptom Day

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

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (11)

Data signed: (b) (4) 26 Apr 2021 23:03:42

Generated On: 09 Jun 2021 17:25:19

| | | |
|----------------------|-------------|----------------------------------|
| | Day 33 | <input type="checkbox"/> |
| | Day 34 | <input type="checkbox"/> |
| | Day 35 | <input type="checkbox"/> |
| | Day 36 | <input type="checkbox"/> |
| | Day 37 | <input type="checkbox"/> |
| | Day 38 | <input type="checkbox"/> |
| | Day 39 | <input type="checkbox"/> |
| | Day 40 | <input type="checkbox"/> |
| Date | 20 JAN 2021 | |
| Assessment Not Done | False | |
| O2 Saturation | 98 % | |
| O2 Saturation Units | % | |
| Temperature | 97.1 F | |
| Chills | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Cough | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Shortness of Breath | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Difficulty Breathing | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |

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Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (11)

Data signed: (b) (4) 26 Apr 2021 23:03:42

Generated On: 09 Jun 2021 17:25:19

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

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Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (11)

Data signed: (b) (4) 26 Apr 2021 23:03:42

Generated On: 09 Jun 2021 17:25:19

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

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (12)

Data signed: (b) (4) 26 Apr 2021 23:03:42

Generated On: 09 Jun 2021 17:25:19

Symptom Day

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

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Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (12)

Data signed: (b) (4) 26 Apr 2021 23:03:42

Generated On: 09 Jun 2021 17:25:19

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

| | |
|------|-------------|
| Date | 21 JAN 2021 |
|------|-------------|

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

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

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

| | |
|-------------|--------|
| Temperature | 97.2 F |
|-------------|--------|

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

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

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

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

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EAB) (1725)

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Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (12)

Data signed: (b) (4) 26 Apr 2021 23:03:42

Generated On: 09 Jun 2021 17:25:19

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

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Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (12)

Data signed: (b) (4) 26 Apr 2021 23:03:42

Generated On: 09 Jun 2021 17:25:19

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

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Folder: Covid-19 Assessment 12 Jan 2021

Form: COVID Diagnostic Test

Data signed: (b) (4) 26 Apr 2021 23:03:42

Generated On: 09 Jun 2021 17:25:19

| | |
|---|--|
| Date of Visit | 12 JAN 2021 |
| Was the Subject Tested For SARS-CoV-2 by RT-PCR? | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Did Subject Test Positive For SARS-CoV-2 by RT-PCR? | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Date of Test | 12 JAN 2021 |
| Type of Test Performed | Nasopharyngeal Swab <input type="radio"/> Nasal Swab <input checked="" type="radio"/> Saliva Test <input type="radio"/> Other <input type="radio"/> |
| Other, specify | |
| Was this diagnostic test performed at a lab other than the Study Central Lab? | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| If yes, provide lab information below | |
| Lab/ Institution Test Performed | |
| CLIA Certified? | Yes <input type="radio"/> No <input type="radio"/> |
| COVID-19 Positive (CSA Programming Field Only) | 0 |

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Folder: Covid-19 Assessment 12 Jan 2021

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 26 Apr 2021 23:03:42

Generated On: 09 Jun 2021 17:25:19

[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

US3402284

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 26 Apr 2021 23:03:42

Generated On: 09 Jun 2021 17:25:19

| Visit | Was Saliva Collected? | Date of Collection |
|--------|------------------------|--------------------|
| Day 3 | Yes | 14 JAN 2021 |
| Day 5 | Yes | 16 JAN 2021 |
| Day 7 | NA (COVID-19 Negative) | |
| Day 9 | No | |
| Day 14 | No | |
| Day 21 | No | |
| Day 28 | No | |

US3402284

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 26 Apr 2021 23:03:42

Generated On: 09 Jun 2021 17:25:19

| | |
|---|---|
| Was this visit performed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Visit date (dd MMM yyyy) | 12 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 | SICKD1 |

US3402284

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 26 Apr 2021 23:03:42

Generated On: 09 Jun 2021 17:25:19

| | |
|-------------------------------------|---------------------------------------|
| Were vital signs assessed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Date of assessment (dd MMM yyyy) | 12 JAN 2021 |
| Time of assessment (00:00-23:59) | 12:20 (24 HR) |
| Vital Signs Date and Time (derived) | 12 JAN 2021 12:20 |
| Height (xxx.x) | ND - Not Done |
| Weight (xxx.x) | ND - Not Done |
| Temperature (xxx.x) | 36.5 C |
| Route of measurement | Oral <input checked="" type="radio"/> |
| | Axillary <input type="radio"/> |
| | Other <input type="radio"/> |
| If Other, specify | |
| Pulse (xxx) | 93 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 14 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 160 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 92 mmHg |
| Diastolic Blood Pressure units | MMHG |
| Height (derived) | |
| Weight (derived) | |

US3402284

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Apr 2021 23:03:42

Generated On: 09 Jun 2021 17:25:19

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

12 JAN 2021

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

US3402284

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 26 Apr 2021 23:03:42

Generated On: 09 Jun 2021 17:25:19

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

12 JAN 2021

US3402284

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

Form: Visit Date

Data signed: (b) (4) 26 Apr 2021 23:03:42

Generated On: 09 Jun 2021 17:25:19

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

| | |
|--------------------------|-------------|
| Visit date (dd MMM yyyy) | 29 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 |
|------------|---------------|

US3402284

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

Form: Unblinding

Data signed: (b) (4) 26 Apr 2021 23:03:42

Generated On: 09 Jun 2021 17:25:19

Date of updated informed consent (*dd MMM yyyy*) 06 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*) 29 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 _____

US3402284

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Apr 2021 23:03:42

Generated On: 09 Jun 2021 17:25:19

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

29 JAN 2021

Collection time (00:00-23:59)

07:45 (24 HR)

Collection date and time (derived)

29 JAN 2021 07:45

US3402284

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 26 Apr 2021 23:03:42

Generated On: 09 Jun 2021 17:25:19

| | |
|---------------------------|--------------------------------------|
| Was the sample collected? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |

| | |
|-------------------------------|-------------|
| Collection date (dd MMM yyyy) | 29 JAN 2021 |
|-------------------------------|-------------|

| | |
|---------------------------------|-------|
| Collection time (00:00 - 23:59) | 07:41 |
|---------------------------------|-------|

| | |
|------------------------------------|-------------------|
| Collection Date and Time (derived) | 29 JAN 2021 07:41 |
|------------------------------------|-------------------|

US3402284

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 14 Mar 2021 14:43:49

Generated On: 09 Jun 2021 17:25:19

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3402284

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 08 Apr 2021 23:35:49

Generated On: 09 Jun 2021 17:25:19

| | |
|--|--|
| AEID | USA-US059-2020-MRNA-1273-P30 1000004 |
| Adverse event | KIDNEY STONE |
| 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 SEP 2020 |
| Start time (00:00-23:59) | |
| AE start date and time (derived) | |
| Ongoing? | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| If not Ongoing, end date (dd MMM yyyy) | 23 SEP 2020 |
| 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) | 22 SEP 2020 |
| Hospital Discharge Date (dd MMM yyyy) | 23 SEP 2020 |
| Admitted to ICU? | Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/> |

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 08 Apr 2021 23:35:49

Generated On: 09 Jun 2021 17:25:19

| | |
|--|--|
| 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 <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 | True |
| 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 | |

US3402284

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 08 Apr 2021 23:35:49

Generated On: 09 Jun 2021 17:25:19

SUBJECT HAD SEVERE PAIN
THE MORNING OF 22SEP2020.
HE WENT TO THE ER AND WAS
ADMITTED FOR EMERGENCY
LITHOTRIPSY. PROCEDURE
WITH STENT PLACEMENT WAS
PERFORMED. SUBJECT WAS
KEPT OVER NIGHT AND
DISCHARGED 23SEP2020 AT
11:30. SUBJECT HAD A WHITE
BLOOD COUNT OF 15.1UL,
NORMAL IS 10.3 UL, CT
ABDOMEN AND PELVIS: LEFT
OBSTRUCTIVE UROPATHY DUE
TO 4.5MM DISTAL URETERAL
STONE. SUBJECT WAS GIVEN
CEFTRIAZONE 1G IV DAILY,
HEPARIN 5,000 UNITS Q12H,
KETOROLAC 30MG IV Q6H,
TAMSULOSIN 0.4 MG PO DAILY.
SUBJECT WAS ALSO GIVEN
SODIUM CHLORIDE 0.9%
100ML/HR. COVID-19 TESTING
WAS PERFORMED 22SEP2020
RESULT WAS NEGATIVE.

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

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 08 Apr 2021 23:35:49

Generated On: 09 Jun 2021 17:25:19

AEID

Adverse event FATIGUE

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) 8 AUG 2020

Start time (00:00-23:59) 06:00 (24 HR)

AE start date and time (derived) 8 AUG 2020 06:00

Ongoing? Yes ☐
No ☒

If not Ongoing, end date (dd MMM yyyy) 21 AUG 2020

End time (00:00-23:59) 15:00 (24 HR)

AE End Date and Time (derived) 21 AUG 2020 15:00

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 (2)

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

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 08 Apr 2021 23:35:49

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AEID

Adverse event

JOINT ACHES

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)

8 AUG 2020

Start time (00:00-23:59)

06:00 (24 HR)

AE start date and time (derived)

8 AUG 2020 06:00

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

19 AUG 2020

End time (00:00-23:59)

14:00 (24 HR)

AE End Date and Time (derived)

19 AUG 2020 14:00

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 (3)

Data signed: (b) (4) 08 Apr 2021 23:35:49

Generated On: 09 Jun 2021 17:25:19

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

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 08 Apr 2021 23:35:49

Generated On: 09 Jun 2021 17:25:19

AEID

Adverse event

MUSCLE ACHES

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)

8 AUG 2020

Start time (00:00-23:59)

06:00 (24 HR)

AE start date and time (derived)

8 AUG 2020 06:00

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

21 AUG 2020

End time (00:00-23:59)

16:30 (24 HR)

AE End Date and Time (derived)

21 AUG 2020 16:30

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 (4)

Data signed: (b) (4) 08 Apr 2021 23:35:49

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

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 08 Apr 2021 23:35:49

Generated On: 09 Jun 2021 17:25:19

AEID

Adverse event JOINT ACHES

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) 10 SEP 2020

Start time (00:00-23:59) 06:35 (24 HR)

AE start date and time (derived) 10 SEP 2020 06:35

Ongoing? Yes ☐
No ☒

If not Ongoing, end date (dd MMM yyyy) 27 SEP 2020

End time (00:00-23:59) 18:30 (24 HR)

AE End Date and Time (derived) 27 SEP 2020 18:30

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 (5)

Data signed: (b) (4) 08 Apr 2021 23:35:49

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

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 08 Apr 2021 23:35:49

Generated On: 09 Jun 2021 17:25:19

AEID

Adverse event

MUSCLE ACHES

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)

11 SEP 2020

Start time (00:00-23:59)

07:44 (24 HR)

AE start date and time (derived)

11 SEP 2020 07:44

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

02 OCT 2020

End time (00:00-23:59)

15:00 (24 HR)

AE End Date and Time (derived)

02 OCT 2020 15:00

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 (6)

Data signed: (b) (4) 08 Apr 2021 23:35:49

Generated On: 09 Jun 2021 17:25:19

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

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 08 Apr 2021 23:35:51

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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) 26 Apr 2021 23:03:42

Generated On: 09 Jun 2021 17:25:19

Name of Medication MULTIVITAMIN (CENTRUM SILVER)

Prophylaxis Yes ☐
No ☒

Indication DIETARY SUPPLEMENT

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 26 Apr 2021 23:03:42

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| | | |
|--|--------------------------|----------------------------------|
| | Intraocular | <input type="radio"/> |
| | Intramuscular | <input type="radio"/> |
| | Respiratory (Inhalation) | <input type="radio"/> |
| | Intralesional | <input type="radio"/> |
| | Intraperitoneal | <input type="radio"/> |
| | Nasal | <input type="radio"/> |
| | Vaginal | <input type="radio"/> |
| | Rectal | <input type="radio"/> |
| | Intravenous | <input type="radio"/> |
| | Intravenous Bolus | <input type="radio"/> |
| | Intravenous Drip | <input type="radio"/> |
| | Other | <input type="radio"/> |
| If route of administration is Other, specify _____ | | |
| Start date (dd MMM yyyy) | UN | UNK 2000 |
| 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"/> |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 26 Apr 2021 23:03:42

Generated On: 09 Jun 2021 17:25:19

Name of Medication ASPIRIN

Prophylaxis Yes ☒
No ☐

Indication CARDIAC PROPHYLAXIS

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 ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 26 Apr 2021 23:03:42

Generated On: 09 Jun 2021 17:25:19

| | | |
|--|--------------------------|----------------------------------|
| | 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 2000 |
| 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 (3)

Data signed: (b) (4) 26 Apr 2021 23:03:42

Generated On: 09 Jun 2021 17:25:19

Name of Medication METFORMIN

Prophylaxis Yes ☐
No ☒

Indication TYPE 2 DIABETES

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 (3)

Data signed: (b) (4) 26 Apr 2021 23:03:42

Generated On: 09 Jun 2021 17:25:19

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 26 Apr 2021 23:03:42

Generated On: 09 Jun 2021 17:25:19

Name of Medication METOPROLOL

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 26 Apr 2021 23:03:42

Generated On: 09 Jun 2021 17:25:19

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 26 Apr 2021 23:03:42

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Name of Medication BENAZEPRIL

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 26 Apr 2021 23:03:42

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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) | UN UNK 2000 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input checked="" type="radio"/> |
| | No | <input type="radio"/> |
| If not Ongoing, End date (dd MMM yyyy) _____ | | |
| Was this medication taken for solicited event? | Yes | <input type="radio"/> |
| | No | <input checked="" type="radio"/> |
| Separate Dosage Number (derived) | 1 | |
| Interval Dosage Unit Number (derived) | 1 | |
| Interval Dosage Definition (derived) | 802 | <input type="radio"/> |
| | 803 | <input type="radio"/> |
| | 804 | <input checked="" type="radio"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 26 Apr 2021 23:03:42

Generated On: 09 Jun 2021 17:25:19

Name of Medication NAPROXEN

Prophylaxis Yes ☐
No ☒

Indication OSTEOARTHRITIS LEFT HIP

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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US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 26 Apr 2021 23:03:42

Generated On: 09 Jun 2021 17:25:19

| | | |
|--|--------------------------|----------------------------------|
| | 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 1982 |
| 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 (7)

Data signed: (b) (4) 26 Apr 2021 23:03:42

Generated On: 09 Jun 2021 17:25:19

Name of Medication CYCLOBENZAPRINE

Prophylaxis Yes ☐
No ☒

Indication PINCHED NERVE LEFT SHOULDER

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 26 Apr 2021 23:03:42

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| | | |
|--|--------------------------|----------------------------------|
| | Intraocular | <input type="radio"/> |
| | Intramuscular | <input type="radio"/> |
| | Respiratory (Inhalation) | <input type="radio"/> |
| | Intralesional | <input type="radio"/> |
| | Intraperitoneal | <input type="radio"/> |
| | Nasal | <input type="radio"/> |
| | Vaginal | <input type="radio"/> |
| | Rectal | <input type="radio"/> |
| | Intravenous | <input type="radio"/> |
| | Intravenous Bolus | <input type="radio"/> |
| | Intravenous Drip | <input type="radio"/> |
| | Other | <input type="radio"/> |
| If route of administration is Other, specify | | |
| Start date (dd MMM yyyy) | UN FEB 2020 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input checked="" type="radio"/> |
| | No | <input type="radio"/> |
| If not Ongoing, End date (dd MMM yyyy) | | |
| Was this medication taken for solicited event? | Yes | <input type="radio"/> |
| | No | <input checked="" type="radio"/> |
| Separate Dosage Number (derived) | 1 | |
| Interval Dosage Unit Number (derived) | 1 | |
| Interval Dosage Definition (derived) | 802 | <input type="radio"/> |
| | 803 | <input type="radio"/> |
| | 804 | <input checked="" type="radio"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 26 Apr 2021 23:03:42

Generated On: 09 Jun 2021 17:25:19

Name of Medication ATORVASTATIN CALCIUM

Prophylaxis Yes ☐
No ☒

Indication HYPERCHOLESTEROLEMIA

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 26 Apr 2021 23:03:42

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 26 Apr 2021 23:03:42

Generated On: 09 Jun 2021 17:25:19

Name of Medication ALLOPURINOL

Prophylaxis Yes ☐
No ☒

Indication GOUT

Dose per administration 300

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) 26 Apr 2021 23:03:42

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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) | UN UNK 2005 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input checked="" type="radio"/> |
| | No | <input type="radio"/> |
| If not Ongoing, End date (dd MMM yyyy) _____ | | |
| Was this medication taken for solicited event? | Yes | <input type="radio"/> |
| | No | <input checked="" type="radio"/> |
| Separate Dosage Number (derived) | 1 | |
| Interval Dosage Unit Number (derived) | 1 | |
| Interval Dosage Definition (derived) | 802 | <input type="radio"/> |
| | 803 | <input type="radio"/> |
| | 804 | <input checked="" type="radio"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 26 Apr 2021 23:03:42

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Name of Medication FLUTICASONE PROPIONATE

Prophylaxis Yes ☐
No ☒

Indication SLEEP APNEA

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 (10)

Data signed: (b) (4) 26 Apr 2021 23:03:42

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| | | |
|--|--------------------------|-------------------------------------|
| | Intramuscular | <input type="checkbox"/> |
| | Respiratory (Inhalation) | <input type="checkbox"/> |
| | Intralesional | <input type="checkbox"/> |
| | Intraperitoneal | <input type="checkbox"/> |
| | Nasal | <input checked="" type="checkbox"/> |
| | Vaginal | <input type="checkbox"/> |
| | Rectal | <input type="checkbox"/> |
| | Intravenous | <input type="checkbox"/> |
| | Intravenous Bolus | <input type="checkbox"/> |
| | Intravenous Drip | <input type="checkbox"/> |
| | Other | <input type="checkbox"/> |
| If route of administration is Other, specify _____ | | |
| Start date (dd MMM yyyy) | UN UNK 2016 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input checked="" type="checkbox"/> |
| | No | <input type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy) _____ | | |
| Was this medication taken for solicited event? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| Separate Dosage Number (derived) | 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 (11)

Data signed: (b) (4) 26 Apr 2021 23:03:42

Generated On: 09 Jun 2021 17:25:19

Name of Medication IBUPROFEN

Prophylaxis Yes ☐
No ☒

Indication HEADACHE/MILD MUSCLE AND JOINT ACES

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 26 Apr 2021 23:03:42

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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) | | 13 SEP 2020 |
| Start date completely unknown | | False |
| Ongoing? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy) | | 15 SEP 2020 |
| Was this medication taken for solicited event? | Yes | <input checked="" type="checkbox"/> |
| | No | <input type="checkbox"/> |
| Separate Dosage Number (derived) _____ | | |
| Interval Dosage Unit Number (derived) _____ | | |
| Interval Dosage Definition (derived) | 802 | <input type="checkbox"/> |
| | 803 | <input type="checkbox"/> |
| | 804 | <input type="checkbox"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 26 Apr 2021 23:03:42

Generated On: 09 Jun 2021 17:25:19

Name of Medication HYDROCHLOROTHIAZIDE

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

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 ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 26 Apr 2021 23:03:42

Generated On: 09 Jun 2021 17:25:19

| | | |
|--|--------------------------|----------------------------------|
| | 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 2000 | |
| 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 (13)

Data signed: (b) (4) 26 Apr 2021 23:03:42

Generated On: 09 Jun 2021 17:25:19

Name of Medication CEFTRIAXONE

Prophylaxis Yes ☐
No ☒

Indication KIDNEY STONE

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 26 Apr 2021 23:03:42

Generated On: 09 Jun 2021 17:25:19

| | | |
|--|--------------------------|-------------------------------------|
| | 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) | | 23 SEP 2020 |
| Start date completely unknown | | False |
| Ongoing? | Yes | <input checked="" type="checkbox"/> |
| | No | <input type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy) _____ | | |
| Was this medication taken for solicited event? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| Separate Dosage Number (derived) | | 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 (14)

Data signed: (b) (4) 26 Apr 2021 23:03:42

Generated On: 09 Jun 2021 17:25:19

Name of Medication HEPARIN

Prophylaxis Yes ☐
No ☒

Indication KIDNEY STONE

Dose per administration 5000

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) 26 Apr 2021 23:03:42

Generated On: 09 Jun 2021 17:25:19

| | | |
|--|--------------------------------------|-------------------------------------|
| | 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) | 22 SEP 2020 | |
| Start date completely unknown | False | |
| Ongoing? | Yes <input type="checkbox"/> | No <input checked="" type="radio"/> |
| If not Ongoing, End date (dd MMM yyyy) 23 SEP 2020 | | |
| Was this medication taken for solicited event? | Yes <input type="checkbox"/> | No <input checked="" type="radio"/> |
| 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="radio"/> | |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 26 Apr 2021 23:03:42

Generated On: 09 Jun 2021 17:25:19

Name of Medication KETOROLAC

Prophylaxis Yes ☐
No ☒

Indication KIDNEY STONE

Dose per administration 30

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) 26 Apr 2021 23:03:42

Generated On: 09 Jun 2021 17:25:19

| | | |
|--|--------------------------|-------------------------------------|
| | 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) | | 22 SEP 2020 |
| Start date completely unknown | | False |
| Ongoing? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy) | | 23 SEP 2020 |
| Was this medication taken for solicited event? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| Separate Dosage Number (derived) | | 4 |
| Interval Dosage Unit Number (derived) | | 1 |
| Interval Dosage Definition (derived) | 802 | <input type="checkbox"/> |
| | 803 | <input type="checkbox"/> |
| | 804 | <input checked="" type="checkbox"/> |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 26 Apr 2021 23:03:42

Generated On: 09 Jun 2021 17:25:19

Name of Medication TAMSULOSIN

Prophylaxis Yes ☐
No ☒

Indication KIDNEY STONE

Dose per administration 0.4

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

504 of 3231

EAB) (1725)

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 26 Apr 2021 23:03:42

Generated On: 09 Jun 2021 17:25:19

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

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 26 Apr 2021 23:03:42

Generated On: 09 Jun 2021 17:25:19

Name of Medication SODIUM CHLORIDE 0.9%

Prophylaxis Yes ☐
No ☒

Indication KIDNEY STONES

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

100 ML PER HOUR

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

PRODUCTION RELEASE (v12.003

506 of 3231

EAB) (1725)

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 26 Apr 2021 23:03:42

Generated On: 09 Jun 2021 17:25:19

| | | |
|--|--------------------------|-------------------------------------|
| | 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 checked="" type="checkbox"/> |
| | Other | <input type="checkbox"/> |
| If route of administration is Other, specify _____ | | |
| Start date (dd MMM yyyy) | | 22 SEP 2020 |
| Start date completely unknown | | False |
| Ongoing? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy) 23 SEP 2020 | | |
| Was this medication taken for solicited event? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| Separate Dosage Number (derived) _____ | | |
| Interval Dosage Unit Number (derived) _____ | | |
| Interval Dosage Definition (derived) | 802 | <input type="checkbox"/> |
| | 803 | <input type="checkbox"/> |
| | 804 | <input type="checkbox"/> |

US3402284

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 08 Apr 2021 23:35:51

Generated On: 09 Jun 2021 17:25:19

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3402284

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 08 Apr 2021 23:35:51

Generated On: 09 Jun 2021 17:25:19

| Procedure/Surgery date (dd MMM yyyy) | Procedure/Surgery | Indication | If indication is Other, specify |
|---|--------------------------|---------------|---------------------------------|
| 22 SEP 2020 | LITHOTRIPSY | Adverse Event | |
| 22 SEP 2020 | CT OF ABDOMEN AND PELVIS | Adverse Event | |
| 22 SEP 2020 | COMPLETE BLOOD COUNT | Adverse Event | |

US3402284

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:25:19

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

US3402284

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:25:19

| | |
|---|---|
| Date of study discontinuation/completion (<i>dd MMM yyyy</i>) | |
| Reason for discontinuation | AE (specify) <input type="checkbox"/> |
| | SAE (specify) <input type="checkbox"/> |
| | Complete <input type="checkbox"/> |
| | Death <input type="checkbox"/> |
| | Lost To Follow-up <input type="checkbox"/> |
| | Physician decision (specify) <input type="checkbox"/> |
| | Pregnancy <input type="checkbox"/> |
| | Protocol deviation (specify) <input type="checkbox"/> |
| | Study Terminated By Sponsor <input type="checkbox"/> |
| | Withdrawal of consent by participant (specify) <input type="checkbox"/> |
| | Other <input type="checkbox"/> |
| 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 <input type="checkbox"/> |
| | Unknown <input type="checkbox"/> |
| | Other <input type="checkbox"/> |
| If main cause of death is Other, specify | |
| Date of death (<i>dd MMM yyyy</i>) | |
| Was autopsy performed? | Yes <input type="checkbox"/> |
| | No <input type="checkbox"/> |
| | Unknown <input type="checkbox"/> |

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form

Data signed: (b) (4) 26 Apr 2021 23:03:42

Generated On: 09 Jun 2021 17:25:19

| | |
|--|--|
| SAEID | USA-US059-2020-MRNA-1273-P301000004 |
| 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 | FRANK |
| Investigator's Last Name | EDER |
| Site Address: Street | 1290 UPPER FRONT STREET |
| Site Address: City | BINGHAMTON |
| Site Address: State | NY |
| Site Address: Postal Code | 13901 |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 4 |

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form (1)

Data signed: (b) (4) 26 Apr 2021 23:03:42

Generated On: 09 Jun 2021 17:25:19

| | |
|---|--|
| SAEID | USA-US059-2020-MRNA-1273-P301000004 |
| 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 | FRANK |
| Investigator's Last Name | EDER |
| Site Address: Street | 1290 UPPER FRONT STREET |
| Site Address: City | BINGHAMTON |
| Site Address: State | NY |
| Site Address: Postal Code | 13901 |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 4 |
| Date of submission (Pre-filled from custom function) | 25/SEP/2020 15:17 |
| 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 |

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form (2)

Data signed: (b) (4) 26 Apr 2021 23:03:42

Generated On: 09 Jun 2021 17:25:19

| | |
|---|--|
| SAEID | USA-US059-2020-MRNA-1273-P301000004 |
| 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 | FRANK |
| Investigator's Last Name | EDER |
| Site Address: Street | 1290 UPPER FRONT STREET |
| Site Address: City | BINGHAMTON |
| Site Address: State | NY |
| Site Address: Postal Code | 13901 |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 4 |
| Date of submission (Pre-filled from custom function) | 13/OCT/2020 13:01 |
| Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge. | True |

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form (3)

Data signed: (b) (4) 26 Apr 2021 23:03:42

Generated On: 09 Jun 2021 17:25:19

| | |
|---|--|
| SAEID | USA-US059-2020-MRNA-1273-P301000004 |
| 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 | FRANK |
| Investigator's Last Name | EDER |
| Site Address: Street | 1290 UPPER FRONT STREET |
| Site Address: City | BINGHAMTON |
| Site Address: State | NY |
| Site Address: Postal Code | 13901 |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 4 |
| Date of submission (Pre-filled from custom function) | 14/OCT/2020 10:03 |
| 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 |

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form (4)

Data signed: (b) (4) 26 Apr 2021 23:03:42

Generated On: 09 Jun 2021 17:25:19

| | |
|---|--|
| SAEID | USA-US059-2020-MRNA-1273-P301000004 |
| 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 | FRANK |
| Investigator's Last Name | EDER |
| Site Address: Street | 1290 UPPER FRONT STREET |
| Site Address: City | BINGHAMTON |
| Site Address: State | NY |
| Site Address: Postal Code | 13901 |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 4 |
| Date of submission (Pre-filled from custom function) | 30/OCT/2020 10:36 |
| Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge. | True |

Audit

US3402284 (Prod: Meridian Clinical Research, LLC)

US3402284

Form: Participant Creation

Generated On: 09 Jun 2021 17:25:19

[Participant ID](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| User entered 'US3402284' | (b) (4) RWS_ENDPOINT ENDPOINT (b) (4) | 08 Aug 2020 12:10:27 |

US3402284

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:25:19

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:36:43 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered 'Yes (Y)' | (b) (4) Abigail Wine (b) (4) | 08 Aug 2020 12:59:56 |

US3402284

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:36:43 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered '08 AUG 2020' | (b) (4) RWS_ENDPOINT ENDPOINT (b) (4) | 08 Aug 2020 12:10:28 |

US3402284

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:25:19

[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 19:36:43 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered 'Clinic (Clinic)' | (b) (4) Abigail Wine (b) (4) | 08 Aug 2020 12:59:56 |

US3402284

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:25:19

[Folder OID](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:36:43 |
| User entered 'SCRN' | System | 08 Aug 2020 12:59:56 |

US3402284

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:25:19

Date of Birth (MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:36:43 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered (b) (6) 1961' | (b) (4) RWS_ENDPOINT ENDPOINT (b) (4) | 08 Aug 2020 12:10:29 |

US3402284

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:25:19

[Age](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:36:43 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered '58' | (b) (4) Abigail Wine (b) (4) | 08 Aug 2020 13:00:07 |

US3402284

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:25:19

[Age Units](#)

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:36:43 |
| User entered 'YEARS' | System | 08 Aug 2020 13:00:07 |

US3402284

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:25:19

[Age \(Derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:36:43 |
| User entered '59' | System | 08 Aug 2020 13:00:42 |

US3402284

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:25:19

[Sex](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:36:43 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered 'Male (M)' | (b) (4) Abigail Wine (b) (4) | 08 Aug 2020 13:00:07 |

US3402284

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:25:19

[Ethnicity](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:36:43 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)' | (b) (4) Abigail Wine (b) (4) | 08 Aug 2020 13:00:07 |

US3402284

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:25:19

White

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:36:43 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered 'I' | (b) (4) Abigail Wine (b) (4) | 08 Aug 2020 13:00:07 |

US3402284

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:25:19

[Black](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:36:43 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered '0' | (b) (4) Abigail Wine (b) (4) | 08 Aug 2020 13:00:07 |

US3402284

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:25:19

[Asian](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:36:43 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered '0' | (b) (4) Abigail Wine (b) (4) | 08 Aug 2020 13:00:07 |

US3402284

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:25:19

[American Indian or Alaska Native](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:36:43 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered '0' | (b) (4) Abigail Wine (b) (4) | 08 Aug 2020 13:00:07 |

US3402284

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:25:19

[Native Hawaiian or other Pacific Islander](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:36:43 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered '0' | (b) (4) Abigail Wine (b) (4) | 08 Aug 2020 13:00:07 |

US3402284

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:25:19

[Other](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:36:43 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered '0' | (b) (4) Abigail Wine (b) (4) | 08 Aug 2020 13:00:07 |

US3402284

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:25:19

If race is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:36:43 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered empty. | (b) (4) Abigail Wine (b) (4) | 08 Aug 2020 13:00:07 |

US3402284

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:25:19

[Unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:36:43 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered '0' | (b) (4) Abigail Wine (b) (4) | 08 Aug 2020 13:00:07 |

US3402284

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:25:19

[Not reported](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:36:43 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered '0' | (b) (4) Abigail Wine (b) (4) | 08 Aug 2020 13:00:07 |

US3402284

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:25:19

Date of Informed Consent (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:36:43 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered '08 Aug 2020' reason for change: New Information | (b) (4) | 11 Nov 2020 12:40:47 |
| User entered '8 Aug 2020' | Traci Hull (b) (4) | 08 Aug 2020 13:00:42 |
| | Abigail Wine (b) (4) | |
| | (b) (4) | |

US3402284

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:36:43 |
| User entered 'Aug 2020' | System | 08 Aug 2020 13:00:42 |

US3402284

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:36:43 |
| User entered '2020' | System | 08 Aug 2020 13:00:42 |

US3402284

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:25:19

[Protocol Version](#)

| Audit | User | Time (GMT) |
|--------------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:36:43 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered 'Amendment 2 (2)' | (b) (4) Abigail Wine (b) (4) | 08 Aug 2020 13:00:42 |

US3402284

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:36:43 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered 'Yes (Y)' | (b) (4) Abigail Wine (b) (4) | 08 Aug 2020 13:00:42 |

US3402284

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:36:43 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered empty. | (b) (4) Abigail Wine (b) (4) | 08 Aug 2020 13:00:42 |

US3402284

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:25:19

If reason for screen fail is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:36:43 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered empty. | (b) (4) Abigail Wine (b) (4) | 08 Aug 2020 13:00:42 |

US3402284

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:25:19

[Was this participant screened previously?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:36:43 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered 'No (N)' | (b) (4) Abigail Wine (b) (4) | 08 Aug 2020 13:00:42 |

US3402284

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:25:19

[If Yes, previous participant number](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:36:43 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered empty. | (b) (4) RWS_ENDPOINT ENDPOINT (b) (4) | 08 Aug 2020 12:10:28 |

US3402284

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:25:19

[Enrollment Trigger](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:36:43 |
| User entered 'I' | System | 08 Aug 2020 13:00:47 |

US3402284

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:36:43 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered 'Yes (Y)' | (b) (4) Abigail Wine (b) (4) | 08 Aug 2020 13:00:47 |

US3402284

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 17:25:19

[Were any significant conditions reported?](#)

| Audit | User | Time (GMT) |
|---|--------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:36:43 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User closed query 'Per source - please verify and add to medical history - L Hip Replacement - Perthes Disease - UNK/2016.' (Site from CRA). | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 21:11:07 |
| DataPoint Verified. | (b) (4), (b) (6) | 24 Nov 2020 21:11:00 |
| Query 'Per source - please verify and add to medical history - L Hip Replacement - Perthes Disease - UNK/2016.' answered with 'This is in direct correlation to the Left hip osteoarthritis' (Site from CRA). | Jennifer Molstead (b) (4) (b) (4) | 23 Nov 2020 20:57:15 |
| User opened query 'Per source - please verify and add to medical history - L Hip Replacement - Perthes Disease - UNK/2016.' (Site from CRA). | (b) (4), (b) (6) | 20 Nov 2020 20:43:32 |
| User entered 'Yes (Y)' | Traci Hull (b) (4) (b) (4) | 08 Aug 2020 20:31:16 |

US3402284

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:25:19

Condition

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:36:43 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User coded data point as SOC: Metabolism and nutrition disorders, HLG: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Type 2 diabetes mellitus, LLT: Type 2 diabetes mellitus - version MedDRA\23.0. | Coder Import (b) (4) | 08 Aug 2020 20:38:49 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0. | Coder Import (b) (4) | 08 Aug 2020 20:38:49 |
| Data point term sent to Coder | System | 08 Aug 2020 20:38:08 |
| Coding entries removed. | Traci Hull (b) (4) | 08 Aug 2020 20:37:52 |
| User entered 'DIABETES TYPE 2' reason for change: Data Entry Error | Traci Hull (b) (4) | 08 Aug 2020 20:37:52 |
| User coded data point as SOC: Metabolism and nutrition disorders, HLG: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Diabetes mellitus, LLT: Diabetes - version MedDRA\23.0. | Coder Import (b) (4) | 08 Aug 2020 20:32:48 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0. | Coder Import (b) (4) | 08 Aug 2020 20:32:48 |
| Data point term sent to Coder | System | 08 Aug 2020 20:32:06 |
| User entered 'DIABETES' | Traci Hull (b) (4) | 08 Aug 2020 20:31:40 |

US3402284

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:36:43 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered 'UN UNK 2019' | (b) (4) Traci Hull (b) (4) | 08 Aug 2020 20:31:40 |

US3402284

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:25:19

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:36:43 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered '0' | (b) (4) Traci Hull (b) (4) | 08 Aug 2020 20:31:40 |

US3402284

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:25:19

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:36:43 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered 'Yes (Y)' | (b) (4) Traci Hull (b) (4) | 08 Aug 2020 20:31:40 |

US3402284

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:36:43 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered empty. | (b) (4) Traci Hull (b) (4) | 08 Aug 2020 20:31:40 |

US3402284

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:25:19

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:36:43 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered '0' | (b) (4) Traci Hull (b) (4) | 08 Aug 2020 20:31:40 |

US3402284

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:36:43 |
| User entered 'Jan 2019' | System | 08 Aug 2020 20:31:40 |

US3402284

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:36:43 |
| User entered '2019' | System | 08 Aug 2020 20:31:40 |

US3402284

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:36:43 |
| User entered empty. | System | 08 Aug 2020 20:31:40 |

US3402284

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:36:43 |
| User entered empty. | System | 08 Aug 2020 20:31:40 |

US3402284

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:25:19

Condition

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:36:43 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User closed query 'CDM RQ: Previous response states 'CHOLECYSTECTOMY due to gallstones', however there is no record of Gallstones in the patients Medical History. Please verify and update as appropriate.' (Site from DM). | (b) (4) (b) (4), (b) (6) | 19 Oct 2020 14:46:49 |
| Query 'CDM RQ: Previous response states 'CHOLECYSTECTOMY due to gallstones', however there is no record of Gallstones in the patients Medical History. Please verify and update as appropriate.' answered with 'DATA UPDATED' (Site from DM). | Tammy Kohn (b) (4) (b) (4) | 08 Oct 2020 17:50:20 |
| User opened query 'CDM RQ: Previous response states 'CHOLECYSTECTOMY due to gallstones', however there is no record of Gallstones in the patients Medical History. Please verify and update as appropriate.' (Site from DM). | (b) (4), (b) (6) | 01 Oct 2020 13:24:50 |
| User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' (Site from DM). | (b) (4), (b) (6) | 01 Oct 2020 13:24:50 |
| Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' answered with 'CHOLECYSTECTOMY due to gallstones' (Site from DM). | Tammy Kohn (b) (4) (b) (4) | 30 Sep 2020 12:43:09 |
| User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' (Site from DM). | (b) (4), (b) (6) | 28 Sep 2020 17:31:21 |
| User coded data point as SOC: Surgical and medical procedures, HLGT: Hepatobiliary therapeutic procedures, HLT: Biliary tract and gallbladder therapeutic procedures, PT: Cholecystectomy, LLT: Cholecystectomy - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 08 Aug 2020 20:32:48 |

US3402284

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:25:19

[Condition](#)

| Audit | User | Time (GMT) |
|---|----------------------|----------------------|
| User coded data point as Term Coded data point by | Coder Import (b) (4) | 08 Aug 2020 20:32:48 |
| User: Coder System - version MedDRA\\23.0. | (b) (4) | |
| Data point term sent to Coder | System | 08 Aug 2020 20:32:06 |
| User entered 'CHOLECYSTECTOMY' | Traci Hull (b) (4) | 08 Aug 2020 20:32:02 |
| | (b) (4) | |

US3402284

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:36:43 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered 'UN Mar 2019' | (b) (4) Traci Hull (b) (4) | 08 Aug 2020 20:32:02 |

US3402284

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:25:19

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:36:43 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered '0' | (b) (4) Traci Hull (b) (4) (b) (4) | 08 Aug 2020 20:32:02 |

US3402284

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:25:19

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:36:43 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered 'No (N)' reason for change: Data Entry Error | (b) (4) | |
| | Traci Hull (b) (4) | 08 Aug 2020 20:33:17 |
| User entered 'Yes (Y)' | (b) (4) | |
| | Traci Hull (b) (4) | 08 Aug 2020 20:32:02 |
| | (b) (4) | |

US3402284

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:36:43 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered 'UN Mar 2019' reason for change: Data Entry Error | (b) (4) | 08 Aug 2020 20:33:17 |
| User entered empty. | Traci Hull (b) (4) | 08 Aug 2020 20:32:02 |
| | (b) (4) | |

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Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:25:19

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:36:43 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered '0' | (b) (4) Traci Hull (b) (4) (b) (4) | 08 Aug 2020 20:32:02 |

US3402284

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:36:43 |
| User entered 'Mar 2019' | System | 08 Aug 2020 20:32:02 |

US3402284

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:36:43 |
| User entered '2019' | System | 08 Aug 2020 20:32:02 |

US3402284

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:36:43 |
| User entered 'Mar 2019' | System | 08 Aug 2020 20:33:17 |
| User entered empty. | System | 08 Aug 2020 20:32:02 |

US3402284

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:36:43 |
| User entered '2019' | System | 08 Aug 2020 20:33:17 |
| User entered empty. | System | 08 Aug 2020 20:32:02 |

US3402284

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:25:19

[Condition](#)

| Audit | User | Time (GMT) |
|---|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:36:43 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Hips osteoarthritis - version MedDRA\\23.0. | (b) (4) Coder Import (b) (4) | 08 Aug 2020 20:34:48 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 08 Aug 2020 20:34:48 |
| Data point term sent to Coder | System | 08 Aug 2020 20:33:06 |
| User entered 'OSTEOARTHRITIS LEFT HIP' | Traci Hull (b) (4) | 08 Aug 2020 20:32:22 |

US3402284

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:36:43 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered 'UN UNK 1982' | (b) (4) Traci Hull (b) (4) (b) (4) | 08 Aug 2020 20:32:22 |

US3402284

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:25:19

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:36:43 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered '0' | (b) (4) Traci Hull (b) (4) (b) (4) | 08 Aug 2020 20:32:22 |

US3402284

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:25:19

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:36:43 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered 'Yes (Y)' | (b) (4) Traci Hull (b) (4) | 08 Aug 2020 20:32:22 |

US3402284

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:36:43 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered empty. | (b) (4) Traci Hull (b) (4) | 08 Aug 2020 20:32:22 |

US3402284

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:25:19

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:36:43 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered '0' | (b) (4) Traci Hull (b) (4) | 08 Aug 2020 20:32:22 |

US3402284

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:36:43 |
| User entered 'Jan 1982' | System | 08 Aug 2020 20:32:22 |

US3402284

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:36:43 |
| User entered '1982' | System | 08 Aug 2020 20:32:22 |

US3402284

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:36:43 |
| User entered empty. | System | 08 Aug 2020 20:32:22 |

US3402284

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:36:43 |
| User entered empty. | System | 08 Aug 2020 20:32:22 |

US3402284

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:25:19

[Condition](#)

| Audit | User | Time (GMT) |
|---|------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:36:43 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| 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. | (b) (4) Coder Import (b) (4) | 08 Aug 2020 20:34:48 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 08 Aug 2020 20:34:48 |
| Data point term sent to Coder | System | 08 Aug 2020 20:33:06 |
| User entered 'HYPERTENSION' | Traci Hull (b) (4) | 08 Aug 2020 20:32:32 |
| | (b) (4) | |

US3402284

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|---|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:36:43 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered 'UN UNK 2000' reason for change: | (b) (4) | |
| Data Entry Error | Tammy Kohn (b) (4) | 26 Sep 2020 15:06:47 |
| User entered 'UN UNK 2017' | (b) (4) | |
| | Traci Hull (b) (4) | 08 Aug 2020 20:32:32 |
| | (b) (4) | |

US3402284

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:25:19

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:36:43 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered '0' | (b) (4) Traci Hull (b) (4) | 08 Aug 2020 20:32:32 |

US3402284

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:25:19

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:36:43 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered 'Yes (Y)' | (b) (4) Traci Hull (b) (4) (b) (4) | 08 Aug 2020 20:32:32 |

US3402284

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:36:43 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered empty. | (b) (4) Traci Hull (b) (4) | 08 Aug 2020 20:32:32 |

US3402284

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:25:19

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:36:43 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered '0' | (b) (4) Traci Hull (b) (4) | 08 Aug 2020 20:32:32 |

US3402284

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:36:43 |
| User entered 'Jan 2000' | System | 26 Sep 2020 15:06:47 |
| User entered 'Jan 2017' | System | 08 Aug 2020 20:32:32 |

US3402284

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:36:43 |
| User entered '2000' | System | 26 Sep 2020 15:06:47 |
| User entered '2017' | System | 08 Aug 2020 20:32:32 |

US3402284

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:36:43 |
| User entered empty. | System | 08 Aug 2020 20:32:32 |

US3402284

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:36:43 |
| User entered empty. | System | 08 Aug 2020 20:32:32 |

US3402284

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:25:19

Condition

| Audit | User | Time (GMT) |
|---|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:36:43 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User coded data point as SOC: Nervous system disorders, HLGT: Peripheral neuropathies, HLT: Mononeuropathies, PT: Nerve compression, LLT: Pinched nerve - version MedDRA\\23.0. | (b) (4) Coder Import (b) (4) (b) (4) | 14 Sep 2020 16:52:42 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 14 Sep 2020 16:52:42 |
| Data point term sent to Coder | System | 08 Aug 2020 20:33:06 |
| User entered 'PINCHED NERVE LEFT SHOULDER' | Traci Hull (b) (4) (b) (4) | 08 Aug 2020 20:32:52 |

US3402284

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:36:43 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered 'UN Feb 2020' | (b) (4) Traci Hull (b) (4) (b) (4) | 08 Aug 2020 20:32:52 |

US3402284

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:25:19

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:36:43 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered '0' | (b) (4) Traci Hull (b) (4) (b) (4) | 08 Aug 2020 20:32:52 |

US3402284

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:25:19

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:36:43 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered 'Yes (Y)' | (b) (4) Traci Hull (b) (4) (b) (4) | 08 Aug 2020 20:32:52 |

US3402284

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:36:43 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered empty. | (b) (4) Traci Hull (b) (4) | 08 Aug 2020 20:32:52 |

US3402284

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:25:19

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:36:43 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered '0' | (b) (4) Traci Hull (b) (4) | 08 Aug 2020 20:32:52 |

US3402284

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:36:43 |
| User entered 'Feb 2020' | System | 08 Aug 2020 20:32:52 |

US3402284

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:36:43 |
| User entered '2020' | System | 08 Aug 2020 20:32:52 |

US3402284

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:36:43 |
| User entered empty. | System | 08 Aug 2020 20:32:52 |

US3402284

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:36:43 |
| User entered empty. | System | 08 Aug 2020 20:32:52 |

US3402284

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:25:19

[Condition](#)

| Audit | User | Time (GMT) |
|---|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:36:43 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Elevated cholesterol, PT: Hypercholesterolaemia, LLT: Hypercholesterolemia - version MedDRA\\23.0. | (b) (4) Coder Import (b) (4) (b) (4) | 08 Aug 2020 20:34:48 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 08 Aug 2020 20:34:48 |
| Data point term sent to Coder | System | 08 Aug 2020 20:34:07 |
| User entered 'HYPERCHOLESTEROLEMIA' | Traci Hull (b) (4) (b) (4) | 08 Aug 2020 20:33:45 |

US3402284

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:36:43 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered 'UN May 2020' | (b) (4) Traci Hull (b) (4) | 08 Aug 2020 20:33:45 |

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Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:25:19

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:36:43 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered '0' | (b) (4) Traci Hull (b) (4) | 08 Aug 2020 20:33:45 |

US3402284

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:25:19

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:36:43 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered 'Yes (Y)' | (b) (4) Traci Hull (b) (4) | 08 Aug 2020 20:33:45 |

US3402284

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:36:43 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered empty. | (b) (4) Traci Hull (b) (4) | 08 Aug 2020 20:33:45 |

US3402284

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:25:19

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:36:43 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered '0' | (b) (4) Traci Hull (b) (4) | 08 Aug 2020 20:33:45 |

US3402284

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:36:43 |
| User entered 'May 2020' | System | 08 Aug 2020 20:33:45 |

US3402284

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:36:43 |
| User entered '2020' | System | 08 Aug 2020 20:33:45 |

US3402284

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:36:43 |
| User entered empty. | System | 08 Aug 2020 20:33:45 |

US3402284

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:36:43 |
| User entered empty. | System | 08 Aug 2020 20:33:45 |

US3402284

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:25:19

Condition

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:36:43 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User closed query 'Per DM CLR: Please specify the location of gout. 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) | 01 Oct 2020 13:25:14 |
| User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Purine and pyrimidine metabolism disorders, HLT: Disorders of purine metabolism, PT: Gout, LLT: Gout - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 30 Sep 2020 12:41:47 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 30 Sep 2020 12:41:47 |
| Data point term sent to Coder | System | 30 Sep 2020 12:41:20 |
| Query 'Per DM CLR: Please specify the location of gout. 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 'GOUT (right foot)' (Site from DM). | Tammy Kohn (b) (4) (b) (4) | 30 Sep 2020 12:41:12 |
| Coding entries removed. | Tammy Kohn (b) (4) (b) (4) | 30 Sep 2020 12:41:06 |
| User entered 'GOUT (right foot)' reason for change: Data Entry Error | Tammy Kohn (b) (4) (b) (4) | 30 Sep 2020 12:41:06 |
| User opened query 'Per DM CLR: Please specify the location of gout. 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) | 28 Sep 2020 17:31:44 |
| User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Purine and pyrimidine metabolism disorders, HLT: Disorders of purine metabolism, PT: Gout, LLT: Gout - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 08 Aug 2020 20:34:48 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 08 Aug 2020 20:34:48 |
| Data point term sent to Coder | System | 08 Aug 2020 20:34:07 |

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Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:25:19

[Condition](#)

| Audit | User | Time (GMT) |
|---------------------|-------------------------------|----------------------|
| User entered 'GOUT' | Traci Hull (b) (4) (b) (4) | 08 Aug 2020 20:33:58 |

US3402284

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:36:43 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered 'UN UNK 2005' | (b) (4) Traci Hull (b) (4) | 08 Aug 2020 20:33:58 |

US3402284

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:25:19

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:36:43 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered '0' | (b) (4) Traci Hull (b) (4) | 08 Aug 2020 20:33:58 |

US3402284

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:25:19

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:36:43 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered 'Yes (Y)' | (b) (4) Traci Hull (b) (4) | 08 Aug 2020 20:33:58 |

US3402284

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:36:43 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered empty. | (b) (4) Traci Hull (b) (4) | 08 Aug 2020 20:33:58 |

US3402284

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:25:19

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:36:43 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered '0' | (b) (4) Traci Hull (b) (4) (b) (4) | 08 Aug 2020 20:33:58 |

US3402284

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:36:43 |
| User entered 'Jan 2005' | System | 08 Aug 2020 20:33:58 |

US3402284

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:36:43 |
| User entered '2005' | System | 08 Aug 2020 20:33:58 |

US3402284

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:36:43 |
| User entered empty. | System | 08 Aug 2020 20:33:58 |

US3402284

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:36:43 |
| User entered empty. | System | 08 Aug 2020 20:33:58 |

US3402284

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:25:19

[Condition](#)

| Audit | User | Time (GMT) |
|---|--------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:36:43 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory disorders NEC, HLT: Breathing abnormalities, PT: Sleep apnoea syndrome, LLT: Sleep apnea - version MedDRA\\23.0. | (b) (4) (b) (4) Coder Import (b) (4) | 08 Aug 2020 20:35:49 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 08 Aug 2020 20:35:49 |
| Data point term sent to Coder | System | 08 Aug 2020 20:35:07 |
| User entered 'SLEEP APNEA' | Traci Hull (b) (4) (b) (4) | 08 Aug 2020 20:34:14 |

US3402284

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:36:43 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered 'UN UNK 2016' | (b) (4) Traci Hull (b) (4) | 08 Aug 2020 20:34:14 |

US3402284

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:25:19

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:36:43 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered '0' | (b) (4) Traci Hull (b) (4) (b) (4) | 08 Aug 2020 20:34:14 |

US3402284

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:25:19

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:36:43 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered 'Yes (Y)' | (b) (4) Traci Hull (b) (4) (b) (4) | 08 Aug 2020 20:34:14 |

US3402284

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:36:43 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered empty. | (b) (4) Traci Hull (b) (4) | 08 Aug 2020 20:34:14 |

US3402284

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:25:19

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:36:43 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered '0' | (b) (4) Traci Hull (b) (4) (b) (4) | 08 Aug 2020 20:34:14 |

US3402284

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:36:43 |
| User entered 'Jan 2016' | System | 08 Aug 2020 20:34:14 |

US3402284

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:36:43 |
| User entered '2016' | System | 08 Aug 2020 20:34:14 |

US3402284

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:36:43 |
| User entered empty. | System | 08 Aug 2020 20:34:14 |

US3402284

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:36:43 |
| User entered empty. | System | 08 Aug 2020 20:34:14 |

US3402284

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:25:19

Condition

| Audit | User | Time (GMT) |
|---|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:36:43 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 21:11:28 |
| User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Bone disorders (excl congenital and fractures), HLT: Epiphyseal disorders, PT: Perthes disease, LLT: Perthes disease - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 08 Aug 2020 20:35:49 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 08 Aug 2020 20:35:49 |
| Data point term sent to Coder | System | 08 Aug 2020 20:35:07 |
| User entered 'PERTHES DISEASE' | Traci Hull (b) (4) (b) (4) | 08 Aug 2020 20:34:32 |

US3402284

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:25:19

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:36:43 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User closed query 'Per source start date was UNK 2016 - please verify and update accordingly. ' (Site from CRA). | (b) (4) (b) (4), (b) (6) | 25 Nov 2020 13:31:30 |
| DataPoint Verified. | (b) (4), (b) (6) | 25 Nov 2020 13:31:27 |
| Query 'Per source start date was UNK 2016 - please verify and update accordingly. ' answered with 'DATA UPDATED' (Site from CRA). | Tammy Kohn (b) (4) (b) (4) | 24 Nov 2020 22:21:46 |
| DataPoint Un-verified. | Tammy Kohn (b) (4) (b) (4) | 24 Nov 2020 22:21:39 |
| User entered 'UN UNK 2016' reason for change: Data Entry Error | Tammy Kohn (b) (4) (b) (4) | 24 Nov 2020 22:21:39 |
| DataPoint Verified. | (b) (4), (b) (6) | 24 Nov 2020 21:11:29 |
| User opened query 'Per source start date was UNK 2016 - please verify and update accordingly. ' (Site from CRA). | (b) (4), (b) (6) | 24 Nov 2020 21:11:25 |
| User entered 'UN UNK 2017' | Traci Hull (b) (4) (b) (4) | 08 Aug 2020 20:34:32 |

US3402284

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:25:19

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:36:43 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 21:11:30 |
| User entered '0' | Traci Hull (b) (4) (b) (4) | 08 Aug 2020 20:34:32 |

US3402284

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:25:19

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:36:43 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 21:11:31 |
| User entered 'Yes (Y)' | Traci Hull (b) (4) (b) (4) | 08 Aug 2020 20:34:32 |

US3402284

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:36:43 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 21:11:32 |
| User entered empty. | Traci Hull (b) (4) (b) (4) | 08 Aug 2020 20:34:32 |

US3402284

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:25:19

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:36:43 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 21:11:34 |
| User entered '0' | Traci Hull (b) (4) (b) (4) | 08 Aug 2020 20:34:32 |

US3402284

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:36:43 |
| User entered 'Jan 2016' | System | 24 Nov 2020 22:21:39 |
| User entered 'Jan 2017' | System | 08 Aug 2020 20:34:32 |

US3402284

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:36:43 |
| User entered '2016' | System | 24 Nov 2020 22:21:39 |
| User entered '2017' | System | 08 Aug 2020 20:34:32 |

US3402284

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:36:43 |
| User entered empty. | System | 08 Aug 2020 20:34:32 |

US3402284

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:36:43 |
| User entered empty. | System | 08 Aug 2020 20:34:32 |

US3402284

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:25:19

[Condition](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:36:43 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User coded data point as SOC: Hepatobiliary disorders, HLGT: Gallbladder disorders, HLT: Cholecystitis and cholelithiasis, PT: Cholelithiasis, LLT: Gallstones - version MedDRA\\23.0. | Coder Import (b) (4) | 08 Oct 2020 23:45:24 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 08 Oct 2020 23:45:24 |
| Data point term sent to Coder | System | 08 Oct 2020 17:50:40 |
| User entered 'Gallstones' | Tammy Kohn (b) (4) | 08 Oct 2020 17:49:53 |

US3402284

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:36:43 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered 'UN UNK 2018' | (b) (4) Tammy Kohn (b) (4) | 08 Oct 2020 17:49:53 |

US3402284

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:25:19

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:36:43 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered '0' | (b) (4) Tammy Kohn (b) (4) | 08 Oct 2020 17:49:53 |

US3402284

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:25:19

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:36:43 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered 'No (N)' | (b) (4) Tammy Kohn (b) (4) | 08 Oct 2020 17:49:53 |
| | (b) (4) | |

US3402284

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|---|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:36:43 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User closed query 'Stop date is prior to Start date. Please correct.' (Site from System). | (b) (4) | |
| User entered 'UN UNK 2019' reason for change: Data Entry Error | System | 08 Oct 2020 17:50:09 |
| User opened query 'Stop date is prior to Start date. Please correct.' (Site from System). | Tammy Kohn (b) (4) | 08 Oct 2020 17:50:09 |
| User entered 'UN UNK 2011' | (b) (4) | |
| | System | 08 Oct 2020 17:49:53 |
| | Tammy Kohn (b) (4) | 08 Oct 2020 17:49:53 |
| | (b) (4) | |

US3402284

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:25:19

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:36:43 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered '0' | (b) (4) Tammy Kohn (b) (4) | 08 Oct 2020 17:49:53 |
| | (b) (4) | |

US3402284

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:36:43 |
| User entered 'Jan 2018' | System | 08 Oct 2020 17:49:53 |

US3402284

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:36:43 |
| User entered '2018' | System | 08 Oct 2020 17:49:53 |

US3402284

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:36:43 |
| User entered 'Jan 2019' | System | 08 Oct 2020 17:50:09 |
| User entered 'Jan 2011' | System | 08 Oct 2020 17:49:53 |

US3402284

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:36:43 |
| User entered '2019' | System | 08 Oct 2020 17:50:09 |
| User entered '2011' | System | 08 Oct 2020 17:49:53 |

US3402284

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:25:19

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:36:43 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered 'Yes (Y)' | (b) (4) Traci Hull (b) (4) (b) (4) | 08 Aug 2020 20:35:25 |

US3402284

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:25:19

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:36:43 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered '08 Aug 2020' reason for change: New Information | (b) (4) | 11 Nov 2020 12:43:29 |
| User entered '8 Aug 2020' | Traci Hull (b) (4) | 08 Aug 2020 20:35:25 |
| | (b) (4) | |

US3402284

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:36:43 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered '07:58' | (b) (4) Traci Hull (b) (4) | 08 Aug 2020 20:35:25 |

US3402284

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:36:43 |
| User entered '08 Aug 2020 07:58' | System | 11 Nov 2020 12:43:29 |
| User entered '8 Aug 2020 07:58' | System | 08 Aug 2020 20:35:25 |

US3402284

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:36:43 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered '187.2' cm | (b) (4) Traci Hull (b) (4) | 08 Aug 2020 20:35:25 |
| DataPoint set to visible. | (b) (4) System | 08 Aug 2020 13:00:47 |

US3402284

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:36:43 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered '139.8' kg | (b) (4) Traci Hull (b) (4) | 08 Aug 2020 20:35:25 |
| DataPoint set to visible. | (b) (4) System | 08 Aug 2020 13:00:47 |

US3402284

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:25:19

BMI (xxx.x)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:36:43 |
| Amendment Manager: User entered '39.89289' | System | 16 Sep 2020 23:48:29 |
| User entered '39.9' | System | 08 Aug 2020 20:35:25 |
| DataPoint set to visible. | System | 08 Aug 2020 13:00:47 |

US3402284

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:25:19

[BMI units](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:36:43 |
| User entered 'kg/m2' | System | 08 Aug 2020 20:35:25 |
| DataPoint set to visible. | System | 08 Aug 2020 13:00:47 |

US3402284

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:25:19

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:36:43 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4) | 20 Dec 2020 17:48:14 |
| User entered '36.6' C | Tammy Kohn (b) (4) | 08 Aug 2020 20:35:25 |
| | (b) (4) | |

US3402284

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:25:19

[Route of measurement](#)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:36:43 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered empty; reason for change Data Entry Error | (b) (4) | |
| | Tammy Kohn (b) (4) | 20 Dec 2020 17:48:14 |
| | (b) (4) | |
| User entered 'Oral (Oral)' | Traci Hull (b) (4) | 08 Aug 2020 20:35:25 |
| | (b) (4) | |

US3402284

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:25:19

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:36:43 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered empty. | (b) (4) Traci Hull (b) (4) | 08 Aug 2020 20:35:25 |

US3402284

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:25:19

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:36:43 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4) | 20 Dec 2020 17:48:14 |
| User entered '81' | Tammy Kohn (b) (4) | 08 Aug 2020 20:35:25 |
| | (b) (4) | |

US3402284

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:25:19

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:36:43 |
| User entered 'bpm' | System | 08 Aug 2020 20:35:25 |

US3402284

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|---|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:36:43 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4) | 20 Dec 2020 17:48:14 |
| User entered '15' | Tammy Kohn (b) (4) | 08 Aug 2020 20:35:25 |
| | (b) (4) | |

US3402284

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:25:19

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:36:43 |
| User entered 'breaths/min' | System | 08 Aug 2020 20:35:25 |

US3402284

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|---|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:36:43 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4) | 20 Dec 2020 17:48:14 |
| User entered '138' | Tammy Kohn (b) (4) | 08 Aug 2020 20:35:25 |
| | (b) (4) | |

US3402284

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:25:19

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:36:43 |
| User entered 'mmHg' | System | 08 Aug 2020 20:35:25 |

US3402284

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|---|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:36:43 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4) | 20 Dec 2020 17:48:14 |
| User entered '82' | Tammy Kohn (b) (4) | 08 Aug 2020 20:35:25 |
| | (b) (4) | |

US3402284

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:25:19

Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:36:43 |
| User entered 'mmHg' | System | 08 Aug 2020 20:35:25 |

US3402284

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:25:19

[Height \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:36:43 |
| | | |

US3402284

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:25:19

Weight (derived)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:36:43 |
| | | |

US3402284

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:25:19

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:36:43 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered 'Yes (Y)' | (b) (4) | |
| | Traci Hull (b) (4) | 08 Aug 2020 20:35:44 |
| | (b) (4) | |

US3402284

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:25:19

Date of examination (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:36:43 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System). | (b) (4) (b) (4), (b) (6) | 11 Sep 2020 22:30:31 |
| Comment added 'SAME DATE'. | Traci Hull (b) (4) | 11 Sep 2020 18:34:36 |
| User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System). | (b) (4) | 11 Sep 2020 18:34:25 |
| User closed query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System). | System | 11 Sep 2020 18:34:25 |
| User entered '08 Aug 2020' reason for change: Data Entry Error | Traci Hull (b) (4) | 11 Sep 2020 18:34:25 |
| User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System). | (b) (4) | 10 Sep 2020 21:06:15 |
| User entered '8 Aug 2020' | Traci Hull (b) (4) | 08 Aug 2020 20:35:44 |

US3402284

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:25:19

[Healthcare workers](#) (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:36:43 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered 'No (N)' | (b) (4) Traci Hull (b) (4) | 08 Aug 2020 20:36:40 |

US3402284

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:25:19

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:36:43 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered 'No (N)' | (b) (4) Traci Hull (b) (4) | 08 Aug 2020 20:36:40 |

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:25:19

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:36:43 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered 'No (N)' | Traci Hull (b) (4) | 08 Aug 2020 20:36:40 |

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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) | 28 Apr 2021 19:36:43 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered 'No (N)' | Traci Hull (b) (4) | 08 Aug 2020 20:36:40 |

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Folder: Screening

Form: Risk of Exposure

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[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:36:43 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered 'No (N)' | (b) (4) Traci Hull (b) (4) (b) (4) | 08 Aug 2020 20:36:40 |

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:25:19

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:36:43 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered 'No (N)' | Traci Hull (b) (4) | 08 Aug 2020 20:36:40 |

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:25:19

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:36:43 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered 'No (N)' | Traci Hull (b) (4) | 08 Aug 2020 20:36:40 |

US3402284

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:25:19

Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:36:43 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered 'Yes (Y)' | Traci Hull (b) (4) | 08 Aug 2020 20:36:40 |

US3402284

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:25:19

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:36:43 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered 'No (N)' | (b) (4) Traci Hull (b) (4) | 08 Aug 2020 20:36:40 |

US3402284

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:25:19

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:36:43 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered 'No (N)' | Traci Hull (b) (4) | 08 Aug 2020 20:36:40 |

US3402284

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:25:19

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:36:43 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered 'No (N)' | Traci Hull (b) (4) | 08 Aug 2020 20:36:40 |

US3402284

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:25:19

Other

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:36:43 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered 'Yes (Y)' | (b) (4) Traci Hull (b) (4) | 08 Aug 2020 20:36:40 |
| | (b) (4) | |

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:25:19

[Specify](#)

| Audit | User | Time (GMT) |
|--|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:36:43 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered 'CUSTODIAN (b) (6) (b) (6)' | (b) (4) Traci Hull (b) (4) | 08 Aug 2020 20:36:40 |

US3402284

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:25:19

No Risk Identified

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:36:43 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered '0' | (b) (4) Traci Hull (b) (4) | 08 Aug 2020 20:36:40 |
| | (b) (4) | |

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:36:43 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered '0' | (b) (4) Traci Hull (b) (4) | 08 Aug 2020 20:36:40 |

US3402284

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:25:19

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:36:43 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered '0' | Traci Hull (b) (4) | 08 Aug 2020 20:36:40 |

US3402284

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:25:19

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:36:43 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered '0' | (b) (4) Traci Hull (b) (4) (b) (4) | 08 Aug 2020 20:36:40 |

US3402284

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:25:19

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:36:43 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered 'I' | Traci Hull (b) (4) | 08 Aug 2020 20:36:40 |

US3402284

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:36:43 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered '0' | (b) (4) Traci Hull (b) (4) (b) (4) | 08 Aug 2020 20:36:40 |

US3402284

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:25:19

[Other](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:36:43 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered '0' | (b) (4) Traci Hull (b) (4) | 08 Aug 2020 20:36:40 |
| | (b) (4) | |

US3402284

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:25:19

[Specify](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 19:36:43 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered empty. | (b) (4) | |
| | Traci Hull (b) (4) | 08 Aug 2020 20:36:40 |
| | (b) (4) | |

US3402284

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:25:19

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered 'Yes (Y)' | (b) (4) Traci Hull (b) (4) | 08 Aug 2020 20:36:55 |

US3402284

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|---|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered '08 Aug 2020' reason for change: New Information | (b) (4) | 11 Nov 2020 12:44:07 |
| User entered '8 Aug 2020' | Traci Hull (b) (4) | 08 Aug 2020 20:36:55 |
| | (b) (4) | |

US3402284

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|--------------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered 'Clinic (Clinic)' | Traci Hull (b) (4) | 08 Aug 2020 20:36:55 |

US3402284

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:25:19

[Folder OID](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User entered 'VISIT1' | System | 08 Aug 2020 20:36:55 |

US3402284

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered '08 AUG 2020' | (b) (4) RWS_ENDPOINT ENDPOINT (b) (4) | 08 Aug 2020 12:10:30 |

US3402284

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System). | (b) (4) System | 21 Aug 2020 03:03:09 |
| Amendment Manager: Data point set to conformant. | System | 21 Aug 2020 03:03:09 |
| User opened query 'Data entered is non-conformant. Please correct.' (Site from System). | System | 08 Aug 2020 12:10:30 |
| User entered '143108' (non-conformant). | RWS_ENDPOINT ENDPOINT (b) (4) | 08 Aug 2020 12:10:30 |

US3402284

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|---|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered '>=18 and <65 years and at risk (2)' | (b) (4) RWS_ENDPOINT ENDPOINT (b) (4) | 08 Aug 2020 12:10:30 |

US3402284

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:25:19

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) | 27 Mar 2021 18:53:35 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered 'No (N)' | Traci Hull (b) (4) | 08 Aug 2020 20:38:04 |

US3402284

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:25:19

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) | 27 Mar 2021 18:53:35 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered 'No (N)' | Traci Hull (b) (4) | 08 Aug 2020 20:38:04 |

US3402284

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered 'No (N)' | (b) (4) Traci Hull (b) (4) | 08 Aug 2020 20:38:04 |

US3402284

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:25:19

[Diabetes \(Type I, Type 2, or gestational\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered 'Yes (Y)' | (b) (4) Traci Hull (b) (4) (b) (4) | 08 Aug 2020 20:38:04 |

US3402284

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:25:19

[Liver Disease](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered 'No (N)' | (b) (4) Traci Hull (b) (4) | 08 Aug 2020 20:38:04 |

US3402284

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:25:19

Human Immunodeficiency Virus (HIV) infection

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User closed query 'Per CDM: This field requires yes or no. Please complete. ' (Site from DM). | (b) (4) | |
| Query 'Per CDM: This field requires yes or no. Please complete. ' answered with 'DATA UPDATED' (Site from DM). | (b) (4), (b) (6) | 03 Nov 2020 13:51:37 |
| Query 'Per CDM: This field requires yes or no. Please complete. ' answered with 'DATA UPDATED' (Site from DM). | Tammy Kohn (b) (4) | 02 Nov 2020 13:23:47 |
| User entered 'No (N)' | (b) (4) | |
| User opened query 'Per CDM: This field requires yes or no. Please complete. ' (Site from DM). | Tammy Kohn (b) (4) | 02 Nov 2020 13:23:41 |
| Amendment Manager: DataPoint set to visible. | (b) (4) | |
| Amendment Manager inserted this DataPoint. | (b) (4), (b) (6) | 02 Nov 2020 10:39:00 |
| | System | 19 Sep 2020 10:03:49 |
| | System | 19 Sep 2020 04:33:24 |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:25:19

[Height](#)

| Audit | User | Time (GMT) |
|---|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4) | 20 Dec 2020 17:47:49 |
| User entered '187.2' cm | Tammy Kohn (b) (4) | 08 Aug 2020 20:38:56 |
| | (b) (4) | |

US3402284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:25:19

[Weight](#)

| Audit | User | Time (GMT) |
|---|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4) | 20 Dec 2020 17:47:49 |
| User entered '139.8' kg | Tammy Kohn (b) (4) | 08 Aug 2020 20:38:56 |
| | (b) (4) | |

US3402284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:25:19

[Height](#)

| Audit | User | Time (GMT) |
|---|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4) | 20 Dec 2020 17:47:49 |
| User entered '187.2' cm | Tammy Kohn (b) (4) | 08 Aug 2020 20:38:56 |
| | (b) (4) | |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:25:19

[Weight](#)

| Audit | User | Time (GMT) |
|---|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4) | 20 Dec 2020 17:47:49 |
| User entered '139.8' kg | Tammy Kohn (b) (4) | 08 Aug 2020 20:38:56 |
| | (b) (4) | |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:25:19

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User accepted default value 'Pre-Dose (PREDOSE)' | Traci Hull (b) (4) (b) (4) | 08 Aug 2020 20:38:56 |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:25:19

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User closed query 'Data is required. Please complete.' (Site from System). | (b) (4) | |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 08 Aug 2020 20:41:54 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | Traci Hull (b) (4) | 08 Aug 2020 20:41:54 |
| User opened query 'Data is required. Please complete.' (Site from System). | (b) (4) | |
| User entered empty. | System | 08 Aug 2020 20:38:56 |
| | Traci Hull (b) (4) | 08 Aug 2020 20:38:56 |
| | (b) (4) | |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:25:19

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered '08 Aug 2020' reason for change: New Information | Traci Hull (b) (4) | 11 Nov 2020 12:44:35 |
| User entered '8 Aug 2020' reason for change: Data Entry Error | Traci Hull (b) (4) | 08 Aug 2020 20:41:54 |
| User entered empty. | Traci Hull (b) (4) | 08 Aug 2020 20:38:56 |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered '07:58' reason for change: Data Entry Error | Traci Hull (b) (4) | 08 Aug 2020 20:41:54 |
| User entered empty. | Traci Hull (b) (4) | 08 Aug 2020 20:38:56 |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User entered '08 Aug 2020 07:58' | System | 11 Nov 2020 12:44:35 |
| User entered '8 Aug 2020 07:58' | System | 08 Aug 2020 20:41:54 |
| User entered empty. | System | 08 Aug 2020 20:38:56 |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:25:19

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered '36.6' C reason for change: Data Entry Error | Traci Hull (b) (4) | 08 Aug 2020 20:41:54 |
| User entered empty. | Traci Hull (b) (4) | 08 Aug 2020 20:38:56 |

US3402284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:25:19

[Route of measurement](#)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered 'Oral (Oral)' reason for change: Data Entry Error | Traci Hull (b) (4) | 08 Aug 2020 20:41:54 |
| User entered empty. | Traci Hull (b) (4) | 08 Aug 2020 20:38:56 |

US3402284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:25:19

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered empty. | (b) (4) Traci Hull (b) (4) | 08 Aug 2020 20:38:56 |

US3402284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:25:19

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered '81' reason for change: Data Entry Error | (b) (4) | |
| | Traci Hull (b) (4) | 08 Aug 2020 20:41:54 |
| User entered empty. | (b) (4) | |
| | Traci Hull (b) (4) | 08 Aug 2020 20:38:56 |
| | (b) (4) | |

US3402284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:25:19

[Pulse units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User entered 'bpm' | System | 08 Aug 2020 20:41:54 |
| User entered empty. | System | 08 Aug 2020 20:38:56 |

US3402284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|---|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered '15' reason for change: Data Entry Error | Traci Hull (b) (4) | 08 Aug 2020 20:41:54 |
| User entered empty. | Traci Hull (b) (4) | 08 Aug 2020 20:38:56 |

US3402284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:25:19

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User entered 'breaths/min' | System | 08 Aug 2020 20:41:54 |
| User entered empty. | System | 08 Aug 2020 20:38:56 |

US3402284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered '138' reason for change: Data Entry Error | Traci Hull (b) (4) | 08 Aug 2020 20:41:54 |
| User entered empty. | Traci Hull (b) (4) | 08 Aug 2020 20:38:56 |

US3402284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:25:19

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User entered 'mmHg' | System | 08 Aug 2020 20:41:54 |
| User entered empty. | System | 08 Aug 2020 20:38:56 |

US3402284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:25:19

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered '82' reason for change: Data Entry Error | Traci Hull (b) (4) | 08 Aug 2020 20:41:54 |
| User entered empty. | Traci Hull (b) (4) | 08 Aug 2020 20:38:56 |

US3402284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:25:19

[Diastolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User entered 'mmHg' | System | 08 Aug 2020 20:41:54 |
| User entered empty. | System | 08 Aug 2020 20:38:56 |

US3402284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:25:19

[Height](#)

| Audit | User | Time (GMT) |
|---|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4) | 20 Dec 2020 17:47:49 |
| User entered '187.2' cm | Tammy Kohn (b) (4) | 08 Aug 2020 20:38:56 |
| | (b) (4) | |

US3402284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:25:19

[Weight](#)

| Audit | User | Time (GMT) |
|---|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4) | 20 Dec 2020 17:47:49 |
| User entered '139.8' kg | Tammy Kohn (b) (4) | 08 Aug 2020 20:38:56 |
| | (b) (4) | |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:25:19

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User accepted default value 'Post-Dose (POSTDOSE)' | Traci Hull (b) (4) (b) (4) | 08 Aug 2020 20:38:56 |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:25:19

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User closed query 'Data is required. Please complete.' (Site from System). | (b) (4) | |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 08 Aug 2020 20:41:54 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | Traci Hull (b) (4) | 08 Aug 2020 20:41:54 |
| User opened query 'Data is required. Please complete.' (Site from System). | (b) (4) | |
| User entered empty. | System | 08 Aug 2020 20:38:56 |
| | Traci Hull (b) (4) | 08 Aug 2020 20:38:56 |
| | (b) (4) | |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:25:19

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered '08 Aug 2020' reason for change: New Information | Traci Hull (b) (4) | 11 Nov 2020 12:45:02 |
| User entered '8 Aug 2020' reason for change: Data Entry Error | Traci Hull (b) (4) | 08 Aug 2020 20:41:54 |
| User entered empty. | Traci Hull (b) (4) | 08 Aug 2020 20:38:56 |

US3402284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|---|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User closed query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System). | (b) (4) (b) (4), (b) (6) | 17 Aug 2020 14:21:59 |
| Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with '30 MINUTES' (Site from System). | Traci Hull (b) (4) (b) (4) | 08 Aug 2020 20:42:04 |
| 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). | | 08 Aug 2020 20:41:54 |
| User entered '09:25' reason for change: Data Entry Error | Traci Hull (b) (4) (b) (4) | 08 Aug 2020 20:41:54 |
| User entered empty. | Traci Hull (b) (4) (b) (4) | 08 Aug 2020 20:38:56 |

US3402284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User entered '08 Aug 2020 09:25' | System | 11 Nov 2020 12:45:02 |
| User entered '8 Aug 2020 09:25' | System | 08 Aug 2020 20:41:54 |
| User entered empty. | System | 08 Aug 2020 20:38:56 |

US3402284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:25:19

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered '36.6' C reason for change: Data Entry Error | (b) (4) | 08 Aug 2020 20:41:54 |
| User entered empty. | Traci Hull (b) (4) | 08 Aug 2020 20:38:56 |
| | (b) (4) | |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:25:19

[Route of measurement](#)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered 'Oral (Oral)' reason for change: Data Entry Error | Traci Hull (b) (4) | 08 Aug 2020 20:41:54 |
| User entered empty. | Traci Hull (b) (4) | 08 Aug 2020 20:38:56 |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:25:19

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered empty. | (b) (4) Traci Hull (b) (4) | 08 Aug 2020 20:38:56 |

US3402284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:25:19

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered '85' reason for change: Data Entry Error | Traci Hull (b) (4) | 08 Aug 2020 20:41:54 |
| User entered empty. | Traci Hull (b) (4) | 08 Aug 2020 20:38:56 |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:25:19

[Pulse units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User entered 'bpm' | System | 08 Aug 2020 20:41:54 |
| User entered empty. | System | 08 Aug 2020 20:38:56 |

US3402284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|---|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered '15' reason for change: Data Entry Error | Traci Hull (b) (4) | 08 Aug 2020 20:41:54 |
| User entered empty. | Traci Hull (b) (4) | 08 Aug 2020 20:38:56 |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:25:19

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User entered 'breaths/min' | System | 08 Aug 2020 20:41:54 |
| User entered empty. | System | 08 Aug 2020 20:38:56 |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered '138' reason for change: Data Entry Error | Traci Hull (b) (4) | 08 Aug 2020 20:41:54 |
| User entered empty. | Traci Hull (b) (4) | 08 Aug 2020 20:38:56 |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:25:19

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User entered 'mmHg' | System | 08 Aug 2020 20:41:54 |
| User entered empty. | System | 08 Aug 2020 20:38:56 |

US3402284

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:25:19

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered '82' reason for change: Data Entry Error | Traci Hull (b) (4) | 08 Aug 2020 20:41:54 |
| User entered empty. | Traci Hull (b) (4) | 08 Aug 2020 20:38:56 |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:25:19

Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User entered 'mmHg' | System | 08 Aug 2020 20:41:54 |
| User entered empty. | System | 08 Aug 2020 20:38:56 |

US3402284

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:25:19

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered 'Yes (Y)' | (b) (4) Traci Hull (b) (4) | 08 Aug 2020 20:39:51 |

US3402284

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:25:19

Date of examination (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered '08 Aug 2020' reason for change: New Information | Traci Hull (b) (4) | 11 Nov 2020 12:45:15 |
| User entered '8 Aug 2020' | Traci Hull (b) (4) | 08 Aug 2020 20:39:51 |

US3402284

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:25:19

[Was study treatment given?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered 'Yes (Y)' | (b) (4) Abigail Wine (b) (4) | 08 Aug 2020 13:01:15 |

US3402284

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:25:19

[If No, reason not given](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered empty. | (b) (4) Abigail Wine (b) (4) | 08 Aug 2020 13:01:15 |

US3402284

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:25:19

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) | 27 Mar 2021 18:53:35 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered empty. | Abigail Wine (b) (4) | 08 Aug 2020 13:01:15 |

US3402284

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:25:19

[What was the study treatment?](#)

| Audit | User | Time (GMT) |
|-------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User entered 'MRNA-1273 OR PLACEBO' | System | 08 Aug 2020 13:01:15 |

US3402284

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:25:19

What was the treatment date? (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered '08 Aug 2020' reason for change: New Information | Traci Hull (b) (4) | 11 Nov 2020 12:45:30 |
| User entered '8 Aug 2020' | Abigail Wine (b) (4) | 08 Aug 2020 13:01:15 |

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered '08:53' | (b) (4) Abigail Wine (b) (4) | 08 Aug 2020 13:01:15 |

US3402284

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User entered '08 Aug 2020 08:53' | System | 11 Nov 2020 12:45:30 |
| User entered '8 Aug 2020 08:53' | System | 08 Aug 2020 13:01:15 |

US3402284

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|------------------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered 'Left Arm (LEFT ARM)' | Abigail Wine (b) (4) | 08 Aug 2020 13:01:15 |

US3402284

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:25:19

What was the frequency of the study treatment dosing?

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User entered 'ONCE' | System | 08 Aug 2020 13:01:15 |

US3402284

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:25:19

What was the route of administration for the study treatment?

| Audit | User | Time (GMT) |
|------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User entered 'INTRAMUSCULAR' | System | 08 Aug 2020 13:01:15 |

US3402284

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:25:19

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered 'Yes (Y)' | (b) (4) Traci Hull (b) (4) (b) (4) | 08 Aug 2020 20:42:29 |

US3402284

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|---|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered '08 Aug 2020' reason for change: New Information | Traci Hull (b) (4) | 11 Nov 2020 12:45:45 |
| User entered '8 Aug 2020' | Traci Hull (b) (4) | 08 Aug 2020 20:42:29 |

US3402284

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:25:19

[Collection time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered '08:21' | (b) (4) Traci Hull (b) (4) | 08 Aug 2020 20:42:29 |

US3402284

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User entered '08 Aug 2020 08:21' | System | 11 Nov 2020 12:45:45 |
| User entered '8 Aug 2020 08:21' | System | 08 Aug 2020 20:42:29 |

US3402284

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|---|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered '08 Aug 2020' reason for change: New Information | Traci Hull (b) (4) | 11 Nov 2020 12:46:01 |
| User entered '8 Aug 2020' | Traci Hull (b) (4) | 08 Aug 2020 20:42:51 |

US3402284

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:25:19

[Lab Test](#)

| Audit | User | Time (GMT) |
|--|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)' | Traci Hull (b) (4) (b) (4) | 08 Aug 2020 20:42:51 |

US3402284

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:25:19

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered 'Yes (Y)' | (b) (4) Traci Hull (b) (4) (b) (4) | 08 Aug 2020 20:42:51 |

US3402284

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:25:19

[Collection time \(00:00 - 23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered '08:10' | Traci Hull (b) (4) | 08 Aug 2020 20:42:51 |

US3402284

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User entered '08 Aug 2020 08:10' | System | 11 Nov 2020 12:46:01 |
| User entered '8 Aug 2020 08:10' | System | 08 Aug 2020 20:42:51 |

US3402284

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:25:19

[Lab Test](#)

| Audit | User | Time (GMT) |
|--|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)' | Traci Hull (b) (4) (b) (4) | 08 Aug 2020 20:42:51 |

US3402284

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:25:19

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered 'No (N)' | (b) (4) Traci Hull (b) (4) (b) (4) | 08 Aug 2020 20:42:51 |

US3402284

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:25:19

Collection time (00:00 - 23:59)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered empty. | Traci Hull (b) (4) | 08 Aug 2020 20:42:51 |

US3402284

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User entered empty. | System | 08 Aug 2020 20:42:51 |

US3402284

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:25:19

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered 'Yes (Y)' | (b) (4) Traci Hull (b) (4) (b) (4) | 08 Aug 2020 20:42:56 |

US3402284

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:25:19

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User entered 'I' | System | 08 Aug 2020 20:42:56 |

US3402284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| Data entry locked. | System | 08 Aug 2020 13:01:15 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 08 Aug 2020 13:01:15 |

US3402284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:25:19

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-08T09:17:27', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '8ac95e62-828c-4ced-be57-3cc7c59907e9' User entered 'Yes (Y)' | System | 08 Aug 2020 13:18:37 |
| | System | 08 Aug 2020 13:18:37 |

US3402284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:25:19

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-08T09:18:08', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '8ac95e62-828c-4ced-be57-3cc7c59907e9' User entered '97.9' | System | 08 Aug 2020 13:18:37 |
| | System | 08 Aug 2020 13:18:37 |

US3402284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-08T09:18:22', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '8ac95e62-828c-4ced-be57-3cc7c59907e9' | System | 08 Aug 2020 13:18:37 |
| User entered 'No (N)' | System | 08 Aug 2020 13:18:37 |

US3402284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:25:19

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-08T09:18:33', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '8ac95e62-828c-4ced-be57-3cc7c59907e9' User entered '08 Aug 2020 09:18' | System | 08 Aug 2020 13:18:37 |
| | System | 08 Aug 2020 13:18:37 |

US3402284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:25:19

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '08 Aug 2020 09:13' | System | 08 Aug 2020 13:01:15 |

US3402284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:25:19

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '08 Aug 2020 11:43' | System | 08 Aug 2020 13:01:15 |

US3402284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| Data entry locked. | System | 08 Aug 2020 13:01:15 |
| User entered 'Day 1, after vaccination (at home)' | System | 08 Aug 2020 13:01:15 |

US3402284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:25:19

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-08T17:09:52', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'dc6fa212-ec4e-40ce-b437-7363c0323101' User entered 'Yes (Y)' | System | 08 Aug 2020 21:10:29 |
| | System | 08 Aug 2020 21:10:29 |

US3402284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:25:19

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-08T17:10:01', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'dc6fa212-ec4e-40ce-b437-7363c0323101' User entered '97.4' | System | 08 Aug 2020 21:10:29 |
| | System | 08 Aug 2020 21:10:29 |

US3402284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-08T17:10:10', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'dc6fa212-ec4e-40ce-b437-7363c0323101' User entered 'No (N)' | System | 08 Aug 2020 21:10:29 |
| | System | 08 Aug 2020 21:10:29 |

US3402284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:25:19

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-08T17:10:27', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'dc6fa212-ec4e-40ce-b437-7363c0323101' User entered '08 Aug 2020 17:10' | System | 08 Aug 2020 21:10:29 |
| | System | 08 Aug 2020 21:10:29 |

US3402284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:25:19

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '08 Aug 2020 12:38' | System | 08 Aug 2020 13:01:15 |

US3402284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:25:19

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '09 Aug 2020 11:59' | System | 08 Aug 2020 13:01:15 |

US3402284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| Data entry locked. | System | 08 Aug 2020 13:01:15 |
| User entered 'Day 2' | System | 08 Aug 2020 13:01:15 |

US3402284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:25:19

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-09T19:09:41', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'a265a951-4be7-4e2a-8f83-2f4ad87c0ce2' | System | 09 Aug 2020 23:10:11 |
| User entered 'Yes (Y)' | System | 09 Aug 2020 23:10:11 |

US3402284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:25:19

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-09T19:09:50', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'a265a951-4be7-4e2a-8f83-2f4ad87c0ce2' | System | 09 Aug 2020 23:10:11 |
| User entered '98.0' | System | 09 Aug 2020 23:10:11 |

US3402284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-09T19:09:56', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'a265a951-4be7-4e2a-8f83-2f4ad87c0ce2' | System | 09 Aug 2020 23:10:11 |
| User entered 'No (N)' | System | 09 Aug 2020 23:10:11 |

US3402284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:25:19

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-09T19:10:08', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'a265a951-4be7-4e2a-8f83-2f4ad87c0ce2' | System | 09 Aug 2020 23:10:11 |
| User entered '09 Aug 2020 19:10' | System | 09 Aug 2020 23:10:11 |

US3402284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:25:19

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '09 Aug 2020 12:00' | System | 08 Aug 2020 13:01:15 |

US3402284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:25:19

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '10 Aug 2020 11:59' | System | 08 Aug 2020 13:01:15 |

US3402284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| Data entry locked. | System | 08 Aug 2020 13:01:15 |
| User entered 'Day 3' | System | 08 Aug 2020 13:01:15 |

US3402284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:25:19

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-10T18:58:09', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'f72cb5cb-4d74-446c-93e8-33992b22cd68' User entered 'Yes (Y)' | System | 10 Aug 2020 22:58:37 |
| | System | 10 Aug 2020 22:58:37 |

US3402284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:25:19

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-10T18:58:19', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'f72cb5cb-4d74-446c-93e8-33992b22cd68' User entered '97.7' | System | 10 Aug 2020 22:58:37 |
| | System | 10 Aug 2020 22:58:37 |

US3402284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-10T18:58:26', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'f72cb5cb-4d74-446c-93e8-33992b22cd68' User entered 'No (N)' | System | 10 Aug 2020 22:58:37 |
| | System | 10 Aug 2020 22:58:37 |

US3402284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:25:19

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-10T18:58:34', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'f72cb5cb-4d74-446c-93e8-33992b22cd68' User entered '10 Aug 2020 18:58' | System | 10 Aug 2020 22:58:37 |
| | System | 10 Aug 2020 22:58:37 |

US3402284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:25:19

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '10 Aug 2020 12:00' | System | 08 Aug 2020 13:01:15 |

US3402284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:25:19

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '11 Aug 2020 11:59' | System | 08 Aug 2020 13:01:15 |

US3402284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| Data entry locked. | System | 08 Aug 2020 13:01:15 |
| User entered 'Day 4' | System | 08 Aug 2020 13:01:15 |

US3402284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:25:19

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-11T17:12:17', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'fda2ea90-cb2c-4651-aa0d-de02a86a382e' User entered 'Yes (Y)' | System | 11 Aug 2020 21:12:45 |
| | System | 11 Aug 2020 21:12:45 |

US3402284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:25:19

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-11T17:12:29', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'fda2ea90-cb2c-4651-aa0d-de02a86a382e' User entered '97.6' | System | 11 Aug 2020 21:12:45 |
| | System | 11 Aug 2020 21:12:45 |

US3402284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-11T17:12:35', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'fda2ea90-cb2c-4651-aa0d-de02a86a382e' User entered 'No (N)' | System | 11 Aug 2020 21:12:45 |
| | System | 11 Aug 2020 21:12:45 |

US3402284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:25:19

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-11T17:12:41', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'fda2ea90-cb2c-4651-aa0d-de02a86a382e' User entered '11 Aug 2020 17:12' | System | 11 Aug 2020 21:12:45 |
| | System | 11 Aug 2020 21:12:45 |

US3402284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:25:19

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '11 Aug 2020 12:00' | System | 08 Aug 2020 13:01:15 |

US3402284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:25:19

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '12 Aug 2020 11:59' | System | 08 Aug 2020 13:01:15 |

US3402284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| Data entry locked. | System | 08 Aug 2020 13:01:15 |
| User entered 'Day 5' | System | 08 Aug 2020 13:01:15 |

US3402284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:25:19

Was TEMPERATURE taken?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-12T18:40:18', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '51a71c85-ed3e-44d5-9207-1b78583906d0' User entered 'Yes (Y)' | System | 12 Aug 2020 22:40:48 |
| | System | 12 Aug 2020 22:40:48 |

US3402284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:25:19

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-12T18:40:29', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '51a71c85-ed3e-44d5-9207-1b78583906d0' User entered '96.7' | System | 12 Aug 2020 22:40:48 |
| | System | 12 Aug 2020 22:40:48 |

US3402284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-12T18:40:39', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '51a71c85-ed3e-44d5-9207-1b78583906d0' | System | 12 Aug 2020 22:40:48 |
| User entered 'No (N)' | System | 12 Aug 2020 22:40:48 |

US3402284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:25:19

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-12T18:40:46', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '51a71c85-ed3e-44d5-9207-1b78583906d0' User entered '12 Aug 2020 18:40' | System | 12 Aug 2020 22:40:48 |
| | System | 12 Aug 2020 22:40:48 |

US3402284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:25:19

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '12 Aug 2020 12:00' | System | 08 Aug 2020 13:01:15 |

US3402284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:25:19

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '13 Aug 2020 11:59' | System | 08 Aug 2020 13:01:15 |

US3402284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| Data entry locked. | System | 08 Aug 2020 13:01:15 |
| User entered 'Day 6' | System | 08 Aug 2020 13:01:15 |

US3402284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:25:19

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-13T19:48:33', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'ad48b303-793e-4718-a36a-3b2775ba07db' User entered 'Yes (Y)' | System | 13 Aug 2020 23:48:53 |
| | System | 13 Aug 2020 23:48:53 |

US3402284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:25:19

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-13T19:48:41', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'ad48b303-793e-4718-a36a-3b2775ba07db' User entered '97.2' | System | 13 Aug 2020 23:48:53 |
| | System | 13 Aug 2020 23:48:53 |

US3402284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-13T19:48:47', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'ad48b303-793e-4718-a36a-3b2775ba07db' User entered 'No (N)' | System | 13 Aug 2020 23:48:53 |
| | System | 13 Aug 2020 23:48:53 |

US3402284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:25:19

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-13T19:48:51', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'ad48b303-793e-4718-a36a-3b2775ba07db' User entered '13 Aug 2020 19:48' | System | 13 Aug 2020 23:48:53 |
| | System | 13 Aug 2020 23:48:53 |

US3402284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:25:19

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '13 Aug 2020 12:00' | System | 08 Aug 2020 13:01:15 |

US3402284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:25:19

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '14 Aug 2020 11:59' | System | 08 Aug 2020 13:01:15 |

US3402284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| Data entry locked. | System | 08 Aug 2020 13:01:15 |
| User entered 'Day 7' | System | 08 Aug 2020 13:01:15 |

US3402284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:25:19

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-14T20:29:21', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'b962156b-c461-4087-9918-c0997d904a92' | System | 15 Aug 2020 00:29:45 |
| User entered 'Yes (Y)' | System | 15 Aug 2020 00:29:45 |

US3402284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:25:19

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-14T20:29:31', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'b962156b-c461-4087-9918-c0997d904a92' | System | 15 Aug 2020 00:29:45 |
| User entered '97.7' | System | 15 Aug 2020 00:29:45 |

US3402284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-14T20:29:38', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'b962156b-c461-4087-9918-c0997d904a92' | System | 15 Aug 2020 00:29:45 |
| User entered 'No (N)' | System | 15 Aug 2020 00:29:45 |

US3402284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:25:19

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-14T20:29:43', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'b962156b-c461-4087-9918-c0997d904a92' | System | 15 Aug 2020 00:29:45 |
| User entered '14 Aug 2020 20:29' | System | 15 Aug 2020 00:29:45 |

US3402284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:25:19

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '14 Aug 2020 12:00' | System | 08 Aug 2020 13:01:15 |

US3402284

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:25:19

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '15 Aug 2020 11:59' | System | 08 Aug 2020 13:01:15 |

US3402284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| Data entry locked. | System | 08 Aug 2020 13:01:15 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 08 Aug 2020 13:01:15 |

US3402284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:25:19

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-08T09:16:25', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '731eff9c-0697-4ef1-82d7-06326d4ba940' User entered 'None (1)' | System | 08 Aug 2020 13:17:04 |
| | System | 08 Aug 2020 13:17:04 |

US3402284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:25:19

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-08T09:16:39', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '731eff9c-0697-4ef1-82d7-06326d4ba940' | System | 08 Aug 2020 13:17:04 |
| User entered 'No (N)' | System | 08 Aug 2020 13:17:04 |

US3402284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-08T09:16:45', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '731eff9c-0697-4ef1-82d7-06326d4ba940' User entered 'No (N)' | System | 08 Aug 2020 13:17:04 |
| | System | 08 Aug 2020 13:17:04 |

US3402284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:25:19

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-08T09:16:54', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '731eff9c-0697-4ef1-82d7-06326d4ba940' | System | 08 Aug 2020 13:17:04 |
| User entered 'None (1)' | System | 08 Aug 2020 13:17:04 |

US3402284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:25:19

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-08T09:17:01', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '731eff9c-0697-4ef1-82d7-06326d4ba940' User entered '08 Aug 2020 09:17' | System | 08 Aug 2020 13:17:04 |
| | System | 08 Aug 2020 13:17:04 |

US3402284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:25:19

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '08 Aug 2020 09:13' | System | 08 Aug 2020 13:01:15 |

US3402284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:25:19

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '08 Aug 2020 11:43' | System | 08 Aug 2020 13:01:15 |

US3402284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| Data entry locked. | System | 08 Aug 2020 13:01:15 |
| User entered 'Day 1, after vaccination (at home)' | System | 08 Aug 2020 13:01:15 |

US3402284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:25:19

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-08T17:10:54', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'c38dced4-ebff-4314-9f69-54d5d68a543b' User entered 'None (1)' | System | 08 Aug 2020 21:11:35 |
| | System | 08 Aug 2020 21:11:35 |

US3402284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:25:19

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-08T17:10:59', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'c38dced4-ebff-4314-9f69-54d5d68a543b' User entered 'No (N)' | System | 08 Aug 2020 21:11:35 |
| | System | 08 Aug 2020 21:11:35 |

US3402284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-08T17:11:06', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'c38dced4-ebff-4314-9f69-54d5d68a543b' User entered 'No (N)' | System | 08 Aug 2020 21:11:35 |
| | System | 08 Aug 2020 21:11:35 |

US3402284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:25:19

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-08T17:11:20', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'c38dced4-ebff-4314-9f69-54d5d68a543b' User entered 'None (1)' | System | 08 Aug 2020 21:11:35 |
| | System | 08 Aug 2020 21:11:35 |

US3402284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:25:19

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-08T17:11:32', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'c38dced4-ebff-4314-9f69-54d5d68a543b' User entered '08 Aug 2020 17:11' | System | 08 Aug 2020 21:11:35 |
| | System | 08 Aug 2020 21:11:35 |

US3402284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:25:19

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '08 Aug 2020 12:38' | System | 08 Aug 2020 13:01:15 |

US3402284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:25:19

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '09 Aug 2020 11:59' | System | 08 Aug 2020 13:01:15 |

US3402284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| Data entry locked. | System | 08 Aug 2020 13:01:15 |
| User entered 'Day 2' | System | 08 Aug 2020 13:01:15 |

US3402284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:25:19

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-09T19:10:23', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '9d4b641d-c8f6-4931-98a2-6ec934fa4c1c' User entered 'Does not interfere with activity (2)' | System | 09 Aug 2020 23:10:57 |

US3402284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:25:19

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-09T19:10:28', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '9d4b641d-c8f6-4931-98a2-6ec934fa4c1c' User entered 'No (N)' | System | 09 Aug 2020 23:10:57 |
| | System | 09 Aug 2020 23:10:57 |

US3402284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-09T19:10:37', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '9d4b641d-c8f6-4931-98a2-6ec934fa4c1c' User entered 'No (N)' | System | 09 Aug 2020 23:10:57 |
| | System | 09 Aug 2020 23:10:57 |

US3402284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:25:19

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-09T19:10:48', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '9d4b641d-c8f6-4931-98a2-6ec934fa4c1c' User entered 'None (1)' | System | 09 Aug 2020 23:10:57 |
| | System | 09 Aug 2020 23:10:57 |

US3402284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:25:19

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-09T19:10:56', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '9d4b641d-c8f6-4931-98a2-6ec934fa4c1c' User entered '09 Aug 2020 19:10' | System | 09 Aug 2020 23:10:57 |
| | System | 09 Aug 2020 23:10:57 |

US3402284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:25:19

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '09 Aug 2020 12:00' | System | 08 Aug 2020 13:01:15 |

US3402284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:25:19

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '10 Aug 2020 11:59' | System | 08 Aug 2020 13:01:15 |

US3402284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| Data entry locked. | System | 08 Aug 2020 13:01:15 |
| User entered 'Day 3' | System | 08 Aug 2020 13:01:15 |

US3402284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:25:19

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-10T18:58:44', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'fc5d490a-6d2d-4ad4-b741-3cbc0317f9dc' | System | 10 Aug 2020 22:59:15 |
| User entered 'Does not interfere with activity (2)' | System | 10 Aug 2020 22:59:15 |

US3402284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-10T18:58:49', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'fc5d490a-6d2d-4ad4-b741-3cbc0317f9dc' User entered 'No (N)' | System | 10 Aug 2020 22:59:15 |
| | System | 10 Aug 2020 22:59:15 |

US3402284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-10T18:58:55', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'fc5d490a-6d2d-4ad4-b741-3cbc0317f9dc' User entered 'No (N)' | System | 10 Aug 2020 22:59:15 |
| | System | 10 Aug 2020 22:59:15 |

US3402284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:25:19

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-10T18:59:07', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'fc5d490a-6d2d-4ad4-b741-3cbc0317f9dc' User entered 'None (1)' | System | 10 Aug 2020 22:59:15 |
| | System | 10 Aug 2020 22:59:15 |

US3402284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:25:19

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-10T18:59:13', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'fc5d490a-6d2d-4ad4-b741-3cbc0317f9dc' User entered '10 Aug 2020 18:59' | System | 10 Aug 2020 22:59:15 |
| | System | 10 Aug 2020 22:59:15 |

US3402284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:25:19

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '10 Aug 2020 12:00' | System | 08 Aug 2020 13:01:15 |

US3402284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:25:19

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '11 Aug 2020 11:59' | System | 08 Aug 2020 13:01:15 |

US3402284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| Data entry locked. | System | 08 Aug 2020 13:01:15 |
| User entered 'Day 4' | System | 08 Aug 2020 13:01:15 |

US3402284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:25:19

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-11T17:12:50', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '58ffad5f-8580-40f6-b656-bf7bad9e1b0a' | System | 11 Aug 2020 21:13:20 |
| User entered 'None (1)' | System | 11 Aug 2020 21:13:20 |

US3402284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:25:19

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-11T17:12:56', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '58ffad5f-8580-40f6-b656-bf7bad9e1b0a' | System | 11 Aug 2020 21:13:20 |
| User entered 'No (N)' | System | 11 Aug 2020 21:13:20 |

US3402284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-11T17:13:01', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '58ffad5f-8580-40f6-b656-bf7bad9e1b0a' | System | 11 Aug 2020 21:13:20 |
| User entered 'No (N)' | System | 11 Aug 2020 21:13:20 |

US3402284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:25:19

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-11T17:13:11', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '58ffad5f-8580-40f6-b656-bf7bad9e1b0a' | System | 11 Aug 2020 21:13:20 |
| User entered 'None (1)' | System | 11 Aug 2020 21:13:20 |

US3402284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:25:19

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-11T17:13:16', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '58ffad5f-8580-40f6-b656-bf7bad9e1b0a' User entered '11 Aug 2020 17:13' | System | 11 Aug 2020 21:13:20 |
| | System | 11 Aug 2020 21:13:20 |

US3402284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:25:19

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '11 Aug 2020 12:00' | System | 08 Aug 2020 13:01:15 |

US3402284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:25:19

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '12 Aug 2020 11:59' | System | 08 Aug 2020 13:01:15 |

US3402284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| Data entry locked. | System | 08 Aug 2020 13:01:15 |
| User entered 'Day 5' | System | 08 Aug 2020 13:01:15 |

US3402284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:25:19

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-12T18:40:55', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'd684b85a-8502-47dc-a706-881196c62280' User entered 'None (1)' | System | 12 Aug 2020 22:41:19 |
| | System | 12 Aug 2020 22:41:19 |

US3402284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:25:19

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-12T18:40:59', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'd684b85a-8502-47dc-a706-881196c62280' User entered 'No (N)' | System | 12 Aug 2020 22:41:19 |
| | System | 12 Aug 2020 22:41:19 |

US3402284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-12T18:41:05', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'd684b85a-8502-47dc-a706-881196c62280' User entered 'No (N)' | System | 12 Aug 2020 22:41:19 |
| | System | 12 Aug 2020 22:41:19 |

US3402284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:25:19

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-12T18:41:11', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'd684b85a-8502-47dc-a706-881196c62280' | System | 12 Aug 2020 22:41:19 |
| User entered 'None (1)' | System | 12 Aug 2020 22:41:19 |

US3402284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:25:19

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-12T18:41:15', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'd684b85a-8502-47dc-a706-881196c62280' User entered '12 Aug 2020 18:41' | System | 12 Aug 2020 22:41:19 |
| | System | 12 Aug 2020 22:41:19 |

US3402284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:25:19

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '12 Aug 2020 12:00' | System | 08 Aug 2020 13:01:15 |

US3402284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:25:19

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '13 Aug 2020 11:59' | System | 08 Aug 2020 13:01:15 |

US3402284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| Data entry locked. | System | 08 Aug 2020 13:01:15 |
| User entered 'Day 6' | System | 08 Aug 2020 13:01:15 |

US3402284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:25:19

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-13T19:49:04', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '03c452d9-3170-47b0-a41e-421133cec6db' User entered 'None (1)' | System | 13 Aug 2020 23:49:28 |
| | System | 13 Aug 2020 23:49:28 |

US3402284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:25:19

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-13T19:49:09', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '03c452d9-3170-47b0-a41e-421133cec6db' User entered 'No (N)' | System | 13 Aug 2020 23:49:28 |
| | System | 13 Aug 2020 23:49:28 |

US3402284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-13T19:49:14', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '03c452d9-3170-47b0-a41e-421133cec6db' User entered 'No (N)' | System | 13 Aug 2020 23:49:28 |
| | System | 13 Aug 2020 23:49:28 |

US3402284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:25:19

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-13T19:49:22', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '03c452d9-3170-47b0-a41e-421133cec6db' User entered 'None (1)' | System | 13 Aug 2020 23:49:28 |
| | System | 13 Aug 2020 23:49:28 |

US3402284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:25:19

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-13T19:49:26', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '03c452d9-3170-47b0-a41e-421133cec6db' User entered '13 Aug 2020 19:49' | System | 13 Aug 2020 23:49:28 |
| | System | 13 Aug 2020 23:49:28 |

US3402284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:25:19

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '13 Aug 2020 12:00' | System | 08 Aug 2020 13:01:15 |

US3402284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:25:19

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '14 Aug 2020 11:59' | System | 08 Aug 2020 13:01:15 |

US3402284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| Data entry locked. | System | 08 Aug 2020 13:01:15 |
| User entered 'Day 7' | System | 08 Aug 2020 13:01:15 |

US3402284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:25:19

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-14T20:29:59', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '16abdb91-d09e-4478-8c65-d75693200a2a' User entered 'None (1)' | System | 15 Aug 2020 00:30:24 |
| | System | 15 Aug 2020 00:30:24 |

US3402284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:25:19

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-14T20:30:05', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '16abdb91-d09e-4478-8c65-d75693200a2a' User entered 'No (N)' | System | 15 Aug 2020 00:30:24 |
| | System | 15 Aug 2020 00:30:24 |

US3402284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-14T20:30:11', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '16abdb91-d09e-4478-8c65-d75693200a2a' User entered 'No (N)' | System | 15 Aug 2020 00:30:24 |
| | System | 15 Aug 2020 00:30:24 |

US3402284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:25:19

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-14T20:30:17', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '16abdb91-d09e-4478-8c65-d75693200a2a' User entered 'None (1)' | System | 15 Aug 2020 00:30:24 |
| | System | 15 Aug 2020 00:30:24 |

US3402284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:25:19

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-14T20:30:21', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '16abdb91-d09e-4478-8c65-d75693200a2a' User entered '14 Aug 2020 20:30' | System | 15 Aug 2020 00:30:24 |
| | System | 15 Aug 2020 00:30:24 |

US3402284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:25:19

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '14 Aug 2020 12:00' | System | 08 Aug 2020 13:01:15 |

US3402284

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:25:19

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '15 Aug 2020 11:59' | System | 08 Aug 2020 13:01:15 |

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| Data entry locked. | System | 08 Aug 2020 13:01:15 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 08 Aug 2020 13:01:15 |

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:25:19

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-08T09:15:05', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'bbd407ef-3752-4d5b-82ad-e90c635f914e' User entered 'None (0)' | System | 08 Aug 2020 13:16:13 |
| | System | 08 Aug 2020 13:16:13 |

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:25:19

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-08T09:15:12', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'bbd407ef-3752-4d5b-82ad-e90c635f914e' User entered 'None (0)' | System | 08 Aug 2020 13:16:13 |
| | System | 08 Aug 2020 13:16:13 |

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:25:19

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-08T09:15:17', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'bbd407ef-3752-4d5b-82ad-e90c635f914e' User entered 'None (0)' | System | 08 Aug 2020 13:16:13 |
| | System | 08 Aug 2020 13:16:13 |

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:25:19

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-08T09:15:22', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'bbd407ef-3752-4d5b-82ad-e90c635f914e' User entered 'None (0)' | System | 08 Aug 2020 13:16:13 |
| | System | 08 Aug 2020 13:16:13 |

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:25:19

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-08T09:15:27', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'bbd407ef-3752-4d5b-82ad-e90c635f914e' User entered 'None (0)' | System | 08 Aug 2020 13:16:13 |
| | System | 08 Aug 2020 13:16:13 |

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:25:19

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-08T09:15:33', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'bbd407ef-3752-4d5b-82ad-e90c635f914e' User entered 'None (0)' | System | 08 Aug 2020 13:16:13 |
| | System | 08 Aug 2020 13:16:13 |

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-08T09:15:53', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'bbd407ef-3752-4d5b-82ad-e90c635f914e' User entered 'No (N)' | System | 08 Aug 2020 13:16:13 |
| | System | 08 Aug 2020 13:16:13 |

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:25:19

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-08T09:16:11', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'bbd407ef-3752-4d5b-82ad-e90c635f914e' User entered '08 Aug 2020 09:16' | System | 08 Aug 2020 13:16:13 |
| | System | 08 Aug 2020 13:16:13 |

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:25:19

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '08 Aug 2020 09:13' | System | 08 Aug 2020 13:01:15 |

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:25:19

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '08 Aug 2020 11:43' | System | 08 Aug 2020 13:01:15 |

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| Data entry locked. | System | 08 Aug 2020 13:01:15 |
| User entered 'Day 1, after vaccination (at home)' | System | 08 Aug 2020 13:01:15 |

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:25:19

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-08T17:11:51', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'fb13249b-b76c-40aa-81a1-cea942fb5b38' User entered 'None (0)' | System | 08 Aug 2020 21:12:56 |
| | System | 08 Aug 2020 21:12:56 |

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:25:19

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-08T17:12:10', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'fb13249b-b76c-40aa-81a1-cea942fb5b38' | System | 08 Aug 2020 21:12:56 |
| User entered 'No interference with activity (1)' | System | 08 Aug 2020 21:12:56 |

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:25:19

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-08T17:12:20', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'fb13249b-b76c-40aa-81a1-cea942fb5b38' | System | 08 Aug 2020 21:12:56 |
| User entered 'No interference with activity (1)' | System | 08 Aug 2020 21:12:56 |

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:25:19

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-08T17:12:32', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'fb13249b-b76c-40aa-81a1-cea942fb5b38' | System | 08 Aug 2020 21:12:56 |
| User entered 'No interference with activity (1)' | System | 08 Aug 2020 21:12:56 |

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:25:19

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-08T17:12:36', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'fb13249b-b76c-40aa-81a1-cea942fb5b38' User entered 'None (0)' | System | 08 Aug 2020 21:12:56 |
| | System | 08 Aug 2020 21:12:56 |

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:25:19

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-08T17:12:42', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'fb13249b-b76c-40aa-81a1-cea942fb5b38' User entered 'None (0)' | System | 08 Aug 2020 21:12:56 |
| | System | 08 Aug 2020 21:12:56 |

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-08T17:12:49', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'fb13249b-b76c-40aa-81a1-cea942fb5b38' User entered 'No (N)' | System | 08 Aug 2020 21:12:56 |
| | System | 08 Aug 2020 21:12:56 |

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:25:19

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-08T17:12:54', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'fb13249b-b76c-40aa-81a1-cea942fb5b38' User entered '08 Aug 2020 17:12' | System | 08 Aug 2020 21:12:56 |
| | System | 08 Aug 2020 21:12:56 |

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:25:19

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '08 Aug 2020 12:38' | System | 08 Aug 2020 13:01:15 |

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:25:19

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '09 Aug 2020 11:59' | System | 08 Aug 2020 13:01:15 |

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| Data entry locked. | System | 08 Aug 2020 13:01:15 |
| User entered 'Day 2' | System | 08 Aug 2020 13:01:15 |

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:25:19

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-09T19:11:05', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '9e619190-a0a8-4525-91e5-06fbd78735ca' User entered 'None (0)' | System | 09 Aug 2020 23:11:43 |
| | System | 09 Aug 2020 23:11:43 |

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:25:19

FATIGUE

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-09T19:11:12', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '9e619190-a0a8-4525-91e5-06fbd78735ca' User entered 'No interference with activity (1)' | System | 09 Aug 2020 23:11:43 |
| | System | 09 Aug 2020 23:11:43 |

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:25:19

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-09T19:11:18', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '9e619190-a0a8-4525-91e5-06fbd78735ca' User entered 'No interference with activity (1)' | System | 09 Aug 2020 23:11:43 |
| | System | 09 Aug 2020 23:11:43 |

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:25:19

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-09T19:11:23', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '9e619190-a0a8-4525-91e5-06fbd78735ca' User entered 'No interference with activity (1)' | System | 09 Aug 2020 23:11:43 |
| | System | 09 Aug 2020 23:11:43 |

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:25:19

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-09T19:11:27', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '9e619190-a0a8-4525-91e5-06fbd78735ca' User entered 'None (0)' | System | 09 Aug 2020 23:11:43 |
| | System | 09 Aug 2020 23:11:43 |

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:25:19

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-09T19:11:31', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '9e619190-a0a8-4525-91e5-06fbd78735ca' User entered 'None (0)' | System | 09 Aug 2020 23:11:43 |
| | System | 09 Aug 2020 23:11:43 |

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-09T19:11:38', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '9e619190-a0a8-4525-91e5-06fbd78735ca' User entered 'No (N)' | System | 09 Aug 2020 23:11:43 |
| | System | 09 Aug 2020 23:11:43 |

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:25:19

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-09T19:11:42', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '9e619190-a0a8-4525-91e5-06fbd78735ca' User entered '09 Aug 2020 19:11' | System | 09 Aug 2020 23:11:43 |
| | System | 09 Aug 2020 23:11:43 |

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:25:19

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '09 Aug 2020 12:00' | System | 08 Aug 2020 13:01:15 |

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:25:19

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '10 Aug 2020 11:59' | System | 08 Aug 2020 13:01:15 |

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| Data entry locked. | System | 08 Aug 2020 13:01:15 |
| User entered 'Day 3' | System | 08 Aug 2020 13:01:15 |

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:25:19

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-10T18:59:26', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'caa87b47-cb44-4d5a-9f73-dc36fe521f1e' User entered 'None (0)' | System | 10 Aug 2020 23:00:02 |
| | System | 10 Aug 2020 23:00:02 |

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:25:19

FATIGUE

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-10T18:59:31', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'caa87b47-cb44-4d5a-9f73-dc36fe521f1e' User entered 'No interference with activity (1)' | System | 10 Aug 2020 23:00:02 |
| | System | 10 Aug 2020 23:00:02 |

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:25:19

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-10T18:59:35', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'caa87b47-cb44-4d5a-9f73-dc36fe521f1e' User entered 'No interference with activity (1)' | System | 10 Aug 2020 23:00:02 |
| | System | 10 Aug 2020 23:00:02 |

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:25:19

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-10T18:59:41', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'caa87b47-cb44-4d5a-9f73-dc36fe521f1e' User entered 'No interference with activity (1)' | System | 10 Aug 2020 23:00:02 |
| | System | 10 Aug 2020 23:00:02 |

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:25:19

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-10T18:59:45', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'caa87b47-cb44-4d5a-9f73-dc36fe521f1e' User entered 'None (0)' | System | 10 Aug 2020 23:00:02 |
| | System | 10 Aug 2020 23:00:02 |

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:25:19

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-10T18:59:48', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'caa87b47-cb44-4d5a-9f73-dc36fe521f1e' User entered 'None (0)' | System | 10 Aug 2020 23:00:02 |
| | System | 10 Aug 2020 23:00:02 |

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-10T18:59:55', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'caa87b47-cb44-4d5a-9f73-dc36fe521f1e' User entered 'No (N)' | System | 10 Aug 2020 23:00:02 |
| | System | 10 Aug 2020 23:00:02 |

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:25:19

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-10T18:59:59', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'caa87b47-cb44-4d5a-9f73-dc36fe521f1e' User entered '10 Aug 2020 18:59' | System | 10 Aug 2020 23:00:02 |
| | System | 10 Aug 2020 23:00:02 |

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:25:19

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '10 Aug 2020 12:00' | System | 08 Aug 2020 13:01:15 |

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:25:19

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '11 Aug 2020 11:59' | System | 08 Aug 2020 13:01:15 |

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| Data entry locked. | System | 08 Aug 2020 13:01:15 |
| User entered 'Day 4' | System | 08 Aug 2020 13:01:15 |

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:25:19

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-11T17:13:27', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '38b12010-85d7-405a-857f-2a54d0ad14c0' User entered 'None (0)' | System | 11 Aug 2020 21:14:04 |
| | System | 11 Aug 2020 21:14:04 |

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:25:19

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-11T17:13:32', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '38b12010-85d7-405a-857f-2a54d0ad14c0' | System | 11 Aug 2020 21:14:04 |
| User entered 'No interference with activity (1)' | System | 11 Aug 2020 21:14:04 |

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:25:19

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-11T17:13:36', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '38b12010-85d7-405a-857f-2a54d0ad14c0' | System | 11 Aug 2020 21:14:04 |
| User entered 'No interference with activity (1)' | System | 11 Aug 2020 21:14:04 |

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:25:19

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-11T17:13:41', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '38b12010-85d7-405a-857f-2a54d0ad14c0' | System | 11 Aug 2020 21:14:04 |
| User entered 'No interference with activity (1)' | System | 11 Aug 2020 21:14:04 |

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:25:19

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-11T17:13:45', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '38b12010-85d7-405a-857f-2a54d0ad14c0' User entered 'None (0)' | System | 11 Aug 2020 21:14:04 |
| | System | 11 Aug 2020 21:14:04 |

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:25:19

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-11T17:13:48', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '38b12010-85d7-405a-857f-2a54d0ad14c0' User entered 'None (0)' | System | 11 Aug 2020 21:14:04 |
| | System | 11 Aug 2020 21:14:04 |

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-11T17:13:54', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '38b12010-85d7-405a-857f-2a54d0ad14c0' User entered 'No (N)' | System | 11 Aug 2020 21:14:04 |
| | System | 11 Aug 2020 21:14:04 |

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:25:19

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-11T17:13:57', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '38b12010-85d7-405a-857f-2a54d0ad14c0' User entered '11 Aug 2020 17:13' | System | 11 Aug 2020 21:14:04 |
| | System | 11 Aug 2020 21:14:04 |

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:25:19

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '11 Aug 2020 12:00' | System | 08 Aug 2020 13:01:15 |

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:25:19

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '12 Aug 2020 11:59' | System | 08 Aug 2020 13:01:15 |

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| Data entry locked. | System | 08 Aug 2020 13:01:15 |
| User entered 'Day 5' | System | 08 Aug 2020 13:01:15 |

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:25:19

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-12T18:41:26', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'aa798807-54db-423d-a2cc-c9493ea7680e' User entered 'None (0)' | System | 12 Aug 2020 22:42:02 |
| | System | 12 Aug 2020 22:42:02 |

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:25:19

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-12T18:41:31', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'aa798807-54db-423d-a2cc-c9493ea7680e' | System | 12 Aug 2020 22:42:02 |
| User entered 'No interference with activity (1)' | System | 12 Aug 2020 22:42:02 |

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:25:19

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-12T18:41:36', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'aa798807-54db-423d-a2cc-c9493ea7680e' User entered 'No interference with activity (1)' | System | 12 Aug 2020 22:42:02 |
| | System | 12 Aug 2020 22:42:02 |

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:25:19

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-12T18:41:39', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'aa798807-54db-423d-a2cc-c9493ea7680e' | System | 12 Aug 2020 22:42:02 |
| User entered 'No interference with activity (1)' | System | 12 Aug 2020 22:42:02 |

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:25:19

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-12T18:41:43', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'aa798807-54db-423d-a2cc-c9493ea7680e' User entered 'None (0)' | System | 12 Aug 2020 22:42:02 |
| | System | 12 Aug 2020 22:42:02 |

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:25:19

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-12T18:41:47', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'aa798807-54db-423d-a2cc-c9493ea7680e' User entered 'None (0)' | System | 12 Aug 2020 22:42:02 |
| | System | 12 Aug 2020 22:42:02 |

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-12T18:41:56', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'aa798807-54db-423d-a2cc-c9493ea7680e' User entered 'No (N)' | System | 12 Aug 2020 22:42:02 |
| | System | 12 Aug 2020 22:42:02 |

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:25:19

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-12T18:41:59', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'aa798807-54db-423d-a2cc-c9493ea7680e' User entered '12 Aug 2020 18:41' | System | 12 Aug 2020 22:42:02 |
| | System | 12 Aug 2020 22:42:02 |

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:25:19

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '12 Aug 2020 12:00' | System | 08 Aug 2020 13:01:15 |

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:25:19

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '13 Aug 2020 11:59' | System | 08 Aug 2020 13:01:15 |

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| Data entry locked. | System | 08 Aug 2020 13:01:15 |
| User entered 'Day 6' | System | 08 Aug 2020 13:01:15 |

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:25:19

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-13T19:49:34', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '5a602974-6ad4-4e7a-bb2e-822a970a6393' User entered 'None (0)' | System | 13 Aug 2020 23:50:13 |
| | System | 13 Aug 2020 23:50:13 |

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:25:19

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-13T19:49:42', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '5a602974-6ad4-4e7a-bb2e-822a970a6393' | System | 13 Aug 2020 23:50:13 |
| User entered 'No interference with activity (1)' | System | 13 Aug 2020 23:50:13 |

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:25:19

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-13T19:49:46', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '5a602974-6ad4-4e7a-bb2e-822a970a6393' | System | 13 Aug 2020 23:50:13 |
| User entered 'No interference with activity (1)' | System | 13 Aug 2020 23:50:13 |

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:25:19

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-13T19:49:51', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '5a602974-6ad4-4e7a-bb2e-822a970a6393' | System | 13 Aug 2020 23:50:13 |
| User entered 'No interference with activity (1)' | System | 13 Aug 2020 23:50:13 |

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:25:19

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-13T19:49:55', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '5a602974-6ad4-4e7a-bb2e-822a970a6393' User entered 'None (0)' | System | 13 Aug 2020 23:50:13 |
| | System | 13 Aug 2020 23:50:13 |

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:25:19

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-13T19:49:58', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '5a602974-6ad4-4e7a-bb2e-822a970a6393' User entered 'None (0)' | System | 13 Aug 2020 23:50:13 |
| | System | 13 Aug 2020 23:50:13 |

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-13T19:50:06', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '5a602974-6ad4-4e7a-bb2e-822a970a6393' User entered 'No (N)' | System | 13 Aug 2020 23:50:13 |
| | System | 13 Aug 2020 23:50:13 |

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:25:19

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-13T19:50:10', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '5a602974-6ad4-4e7a-bb2e-822a970a6393' User entered '13 Aug 2020 19:50' | System | 13 Aug 2020 23:50:13 |
| | System | 13 Aug 2020 23:50:13 |

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:25:19

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '13 Aug 2020 12:00' | System | 08 Aug 2020 13:01:15 |

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:25:19

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '14 Aug 2020 11:59' | System | 08 Aug 2020 13:01:15 |

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| Data entry locked. | System | 08 Aug 2020 13:01:15 |
| User entered 'Day 7' | System | 08 Aug 2020 13:01:15 |

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:25:19

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-14T20:30:28', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'd36aec1d-ba60-45de-96e6-9f747a4deb54' User entered 'None (0)' | System | 15 Aug 2020 00:31:09 |
| | System | 15 Aug 2020 00:31:09 |

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:25:19

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-14T20:30:36', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'd36aec1d-ba60-45de-96e6-9f747a4deb54' | System | 15 Aug 2020 00:31:09 |
| User entered 'No interference with activity (1)' | System | 15 Aug 2020 00:31:09 |

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:25:19

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-14T20:30:42', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'd36aec1d-ba60-45de-96e6-9f747a4deb54' | System | 15 Aug 2020 00:31:09 |
| User entered 'No interference with activity (1)' | System | 15 Aug 2020 00:31:09 |

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:25:19

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-14T20:30:46', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'd36aec1d-ba60-45de-96e6-9f747a4deb54' | System | 15 Aug 2020 00:31:09 |
| User entered 'No interference with activity (1)' | System | 15 Aug 2020 00:31:09 |

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:25:19

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-14T20:30:50', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'd36aec1d-ba60-45de-96e6-9f747a4deb54' User entered 'None (0)' | System | 15 Aug 2020 00:31:09 |
| | System | 15 Aug 2020 00:31:09 |

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:25:19

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-14T20:30:54', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'd36aec1d-ba60-45de-96e6-9f747a4deb54' User entered 'None (0)' | System | 15 Aug 2020 00:31:09 |
| | System | 15 Aug 2020 00:31:09 |

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-14T20:31:01', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'd36aec1d-ba60-45de-96e6-9f747a4deb54' User entered 'No (N)' | System | 15 Aug 2020 00:31:09 |
| | System | 15 Aug 2020 00:31:09 |

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:25:19

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-14T20:31:04', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'd36aec1d-ba60-45de-96e6-9f747a4deb54' User entered '14 Aug 2020 20:31' | System | 15 Aug 2020 00:31:09 |
| | System | 15 Aug 2020 00:31:09 |

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:25:19

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '14 Aug 2020 12:00' | System | 08 Aug 2020 13:01:15 |

US3402284

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:25:19

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '15 Aug 2020 11:59' | System | 08 Aug 2020 13:01:15 |

US3402284

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| Data entry locked. | System | 13 Aug 2020 23:50:13 |
| User entered 'Day 8' | System | 13 Aug 2020 23:50:13 |

US3402284

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 17:25:19

Select one response below to indicate the intensity of your **FATIGUE**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-15T22:49:20', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'c121a01a-1d5d-4886-af52-c7c4dec7d669' | System | 16 Aug 2020 02:49:37 |
| User entered 'No interference with activity (1)' | System | 16 Aug 2020 02:49:37 |

US3402284

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 17:25:19

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-15T22:49:32', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'c121a01a-1d5d-4886-af52-c7c4dec7d669' | System | 16 Aug 2020 02:49:37 |
| User entered '15 Aug 2020 22:49' | System | 16 Aug 2020 02:49:37 |

US3402284

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 17:25:19

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '15 Aug 2020 12:00' | System | 13 Aug 2020 23:50:13 |

US3402284

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 17:25:19

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '16 Aug 2020 11:59' | System | 13 Aug 2020 23:50:13 |

US3402284

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| Data entry locked. | System | 15 Aug 2020 00:31:09 |
| User entered 'Day 9' | System | 15 Aug 2020 00:31:09 |

US3402284

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 09 Jun 2021 17:25:19

Select one response below to indicate the intensity of your **FATIGUE**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-16T19:17:12', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '8ed4d51e-2a7e-4a6c-b781-720f6f5e9e67' | System | 16 Aug 2020 23:17:25 |
| User entered 'No interference with activity (1)' | System | 16 Aug 2020 23:17:25 |

US3402284

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 09 Jun 2021 17:25:19

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-16T19:17:24', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '8ed4d51e-2a7e-4a6c-b781-720f6f5e9e67' User entered '16 Aug 2020 19:17' | System | 16 Aug 2020 23:17:25 |
| | System | 16 Aug 2020 23:17:25 |

US3402284

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 09 Jun 2021 17:25:19

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '16 Aug 2020 12:00' | System | 15 Aug 2020 00:31:09 |

US3402284

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 09 Jun 2021 17:25:19

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '17 Aug 2020 11:59' | System | 15 Aug 2020 00:31:09 |

US3402284

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| Data entry locked. | System | 16 Aug 2020 02:49:37 |
| User entered 'Day 10' | System | 16 Aug 2020 02:49:37 |

US3402284

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 09 Jun 2021 17:25:19

Select one response below to indicate the intensity of your **FATIGUE**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-17T17:47:41', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '235dad20-4f87-40b5-8ce6-070e54680360' | System | 17 Aug 2020 21:47:52 |
| User entered 'Some interference with activity (2)' | System | 17 Aug 2020 21:47:52 |

US3402284

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 09 Jun 2021 17:25:19

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-17T17:47:47', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '235dad20-4f87-40b5-8ce6-070e54680360' User entered '17 Aug 2020 17:47' | System | 17 Aug 2020 21:47:52 |
| | System | 17 Aug 2020 21:47:52 |

US3402284

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 09 Jun 2021 17:25:19

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '17 Aug 2020 12:00' | System | 16 Aug 2020 02:49:37 |

US3402284

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 09 Jun 2021 17:25:19

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '18 Aug 2020 11:59' | System | 16 Aug 2020 02:49:37 |

US3402284

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(11)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| Data entry locked. | System | 16 Aug 2020 23:17:25 |
| User entered 'Day 11' | System | 16 Aug 2020 23:17:25 |

US3402284

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(11)

Generated On: 09 Jun 2021 17:25:19

Select one response below to indicate the intensity of your **FATIGUE**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-18T21:09:04', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '5ed09058-c479-481e-8ac7-554cb12cde78' | System | 19 Aug 2020 01:09:13 |
| User entered 'No interference with activity (1)' | System | 19 Aug 2020 01:09:13 |

US3402284

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(11)

Generated On: 09 Jun 2021 17:25:19

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-18T21:09:11', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '5ed09058-c479-481e-8ac7-554cb12cde78' | System | 19 Aug 2020 01:09:13 |
| User entered '18 Aug 2020 21:09' | System | 19 Aug 2020 01:09:13 |

US3402284

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(11)

Generated On: 09 Jun 2021 17:25:19

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '18 Aug 2020 12:00' | System | 16 Aug 2020 23:17:25 |

US3402284

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(11)

Generated On: 09 Jun 2021 17:25:19

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '19 Aug 2020 11:59' | System | 16 Aug 2020 23:17:25 |

US3402284

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(12)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| Data entry locked. | System | 17 Aug 2020 21:47:52 |
| User entered 'Day 12' | System | 17 Aug 2020 21:47:52 |

US3402284

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(12)

Generated On: 09 Jun 2021 17:25:19

Select one response below to indicate the intensity of your **FATIGUE**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-19T18:52:26', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'eae2f9cd-4a01-4389-8685-22d4da0fc799' | System | 19 Aug 2020 22:52:36 |
| User entered 'No interference with activity (1)' | System | 19 Aug 2020 22:52:36 |

US3402284

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(12)

Generated On: 09 Jun 2021 17:25:19

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-19T18:52:31', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'eae2f9cd-4a01-4389-8685-22d4da0fc799' | System | 19 Aug 2020 22:52:36 |
| User entered '19 Aug 2020 18:52' | System | 19 Aug 2020 22:52:36 |

US3402284

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(12)

Generated On: 09 Jun 2021 17:25:19

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '19 Aug 2020 12:00' | System | 17 Aug 2020 21:47:52 |

US3402284

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(12)

Generated On: 09 Jun 2021 17:25:19

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '20 Aug 2020 11:59' | System | 17 Aug 2020 21:47:52 |

US3402284

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(13)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| Data entry locked. | System | 19 Aug 2020 01:09:13 |
| User entered 'Day 13' | System | 19 Aug 2020 01:09:13 |

US3402284

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(13)

Generated On: 09 Jun 2021 17:25:19

Select one response below to indicate the intensity of your **FATIGUE**

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-20T18:42:23', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '9d4714ef-340b-4ea2-aa25-9d13a1ee104f' User entered 'No interference with activity (1)' | System | 20 Aug 2020 22:42:31 |
| | | |
| | System | 20 Aug 2020 22:42:31 |

US3402284

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(13)

Generated On: 09 Jun 2021 17:25:19

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-20T18:42:28', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '9d4714ef-340b-4ea2-aa25-9d13a1ee104f' User entered '20 Aug 2020 18:42' | System | 20 Aug 2020 22:42:31 |
| | System | 20 Aug 2020 22:42:31 |

US3402284

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(13)

Generated On: 09 Jun 2021 17:25:19

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '20 Aug 2020 12:00' | System | 19 Aug 2020 01:09:13 |

US3402284

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(13)

Generated On: 09 Jun 2021 17:25:19

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '21 Aug 2020 11:59' | System | 19 Aug 2020 01:09:13 |

US3402284

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(14)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| Data entry locked. | System | 19 Aug 2020 22:52:36 |
| User entered 'Day 14' | System | 19 Aug 2020 22:52:36 |

US3402284

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(14)

Generated On: 09 Jun 2021 17:25:19

Select one response below to indicate the intensity of your **FATIGUE**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-21T19:59:34', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '60d2b570-01dd-495a-a2c5-0119ce58844a' | System | 21 Aug 2020 23:59:54 |
| User entered 'Some interference with activity (2)' | System | 21 Aug 2020 23:59:54 |

US3402284

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(14)

Generated On: 09 Jun 2021 17:25:19

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-21T19:59:50', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '60d2b570-01dd-495a-a2c5-0119ce58844a' User entered '21 Aug 2020 19:59' | System | 21 Aug 2020 23:59:54 |
| | System | 21 Aug 2020 23:59:54 |

US3402284

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(14)

Generated On: 09 Jun 2021 17:25:19

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '21 Aug 2020 12:00' | System | 19 Aug 2020 22:52:36 |

US3402284

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(14)

Generated On: 09 Jun 2021 17:25:19

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '22 Aug 2020 11:59' | System | 19 Aug 2020 22:52:36 |

US3402284

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(15)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| Data entry locked. | System | 20 Aug 2020 22:42:31 |
| User entered 'Day 15' | System | 20 Aug 2020 22:42:31 |

US3402284

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(15)

Generated On: 09 Jun 2021 17:25:19

Select one response below to indicate the intensity of your **FATIGUE**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-22T17:10:50', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '54edcbf4-1caf-46e9-b52c-b97f5b69442a' User entered 'None (0)' | System | 22 Aug 2020 21:11:01 |
| | System | 22 Aug 2020 21:11:01 |

US3402284

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(15)

Generated On: 09 Jun 2021 17:25:19

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-22T17:10:59', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '54edcbf4-1caf-46e9-b52c-b97f5b69442a' User entered '22 Aug 2020 17:10' | System | 22 Aug 2020 21:11:01 |
| | System | 22 Aug 2020 21:11:01 |

US3402284

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(15)

Generated On: 09 Jun 2021 17:25:19

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '22 Aug 2020 12:00' | System | 20 Aug 2020 22:42:31 |

US3402284

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(15)

Generated On: 09 Jun 2021 17:25:19

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '23 Aug 2020 11:59' | System | 20 Aug 2020 22:42:31 |

US3402284

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| Data entry locked. | System | 13 Aug 2020 23:50:13 |
| User entered 'Day 8' | System | 13 Aug 2020 23:50:13 |

US3402284

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 17:25:19

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-15T22:49:46', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'dfeefc7e-4555-49c2-a4c5-7d1c7a158821' | System | 16 Aug 2020 02:49:55 |
| User entered 'No interference with activity (1)' | System | 16 Aug 2020 02:49:55 |

US3402284

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 17:25:19

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-15T22:49:53', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'dfeefc7e-4555-49c2-a4c5-7d1c7a158821' | System | 16 Aug 2020 02:49:55 |
| User entered '15 Aug 2020 22:49' | System | 16 Aug 2020 02:49:55 |

US3402284

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 17:25:19

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '15 Aug 2020 12:00' | System | 13 Aug 2020 23:50:13 |

US3402284

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 17:25:19

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '16 Aug 2020 11:59' | System | 13 Aug 2020 23:50:13 |

US3402284

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| Data entry locked. | System | 15 Aug 2020 00:31:09 |
| User entered 'Day 9' | System | 15 Aug 2020 00:31:09 |

US3402284

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 09 Jun 2021 17:25:19

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-16T19:17:40', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'b0148edf-ac3d-435a-88a2-05f55ceba77e' | System | 16 Aug 2020 23:17:48 |
| User entered 'No interference with activity (1)' | System | 16 Aug 2020 23:17:48 |

US3402284

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 09 Jun 2021 17:25:19

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-16T19:17:44', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'b0148edf-ac3d-435a-88a2-05f55ceba77e' User entered '16 Aug 2020 19:17' | System | 16 Aug 2020 23:17:48 |
| | System | 16 Aug 2020 23:17:48 |

US3402284

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 09 Jun 2021 17:25:19

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '16 Aug 2020 12:00' | System | 15 Aug 2020 00:31:09 |

US3402284

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 09 Jun 2021 17:25:19

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '17 Aug 2020 11:59' | System | 15 Aug 2020 00:31:09 |

US3402284

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(10)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| Data entry locked. | System | 16 Aug 2020 02:49:55 |
| User entered 'Day 10' | System | 16 Aug 2020 02:49:55 |

US3402284

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(10)

Generated On: 09 Jun 2021 17:25:19

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-17T17:48:30', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '4f6a62ff-d8a9-4d00-a5b0-ffa5bd6237d5' | System | 17 Aug 2020 21:48:38 |
| User entered 'Some interference with activity (2)' | System | 17 Aug 2020 21:48:38 |

US3402284

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(10)

Generated On: 09 Jun 2021 17:25:19

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-17T17:48:33', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '4f6a62ff-d8a9-4d00-a5b0-ffa5bd6237d5' | System | 17 Aug 2020 21:48:38 |
| User entered '17 Aug 2020 17:48' | System | 17 Aug 2020 21:48:38 |

US3402284

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(10)

Generated On: 09 Jun 2021 17:25:19

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '17 Aug 2020 12:00' | System | 16 Aug 2020 02:49:55 |

US3402284

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(10)

Generated On: 09 Jun 2021 17:25:19

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '18 Aug 2020 11:59' | System | 16 Aug 2020 02:49:55 |

US3402284

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(11)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| Data entry locked. | System | 16 Aug 2020 23:17:48 |
| User entered 'Day 11' | System | 16 Aug 2020 23:17:48 |

US3402284

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(11)

Generated On: 09 Jun 2021 17:25:19

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-18T21:09:19', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'b6722e0f-f959-4266-a07e-212b75ea834b' User entered 'No interference with activity (1)' | System | 19 Aug 2020 01:09:27 |

US3402284

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(11)

Generated On: 09 Jun 2021 17:25:19

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-18T21:09:23', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'b6722e0f-f959-4266-a07e-212b75ea834b' User entered '18 Aug 2020 21:09' | System | 19 Aug 2020 01:09:27 |
| | System | 19 Aug 2020 01:09:27 |

US3402284

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(11)

Generated On: 09 Jun 2021 17:25:19

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '18 Aug 2020 12:00' | System | 16 Aug 2020 23:17:48 |

US3402284

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(11)

Generated On: 09 Jun 2021 17:25:19

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '19 Aug 2020 11:59' | System | 16 Aug 2020 23:17:48 |

US3402284

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(12)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| Data entry locked. | System | 17 Aug 2020 21:48:38 |
| User entered 'Day 12' | System | 17 Aug 2020 21:48:38 |

US3402284

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(12)

Generated On: 09 Jun 2021 17:25:19

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-19T18:52:46', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '75d09134-8426-41e9-8b3f-7febb89a6a7b' | System | 19 Aug 2020 22:52:53 |
| User entered 'No interference with activity (1)' | System | 19 Aug 2020 22:52:53 |

US3402284

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(12)

Generated On: 09 Jun 2021 17:25:19

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-19T18:52:49', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '75d09134-8426-41e9-8b3f-7febb89a6a7b' User entered '19 Aug 2020 18:52' | System | 19 Aug 2020 22:52:53 |
| | System | 19 Aug 2020 22:52:53 |

US3402284

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(12)

Generated On: 09 Jun 2021 17:25:19

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '19 Aug 2020 12:00' | System | 17 Aug 2020 21:48:38 |

US3402284

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(12)

Generated On: 09 Jun 2021 17:25:19

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '20 Aug 2020 11:59' | System | 17 Aug 2020 21:48:38 |

US3402284

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(13)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| Data entry locked. | System | 19 Aug 2020 01:09:27 |
| User entered 'Day 13' | System | 19 Aug 2020 01:09:27 |

US3402284

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(13)

Generated On: 09 Jun 2021 17:25:19

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-20T18:42:37', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '08ffffbd-7e48-43d9-9423-d7a40b64a2ab' | System | 20 Aug 2020 22:42:44 |
| User entered 'No interference with activity (1)' | System | 20 Aug 2020 22:42:44 |

US3402284

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(13)

Generated On: 09 Jun 2021 17:25:19

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-20T18:42:42', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '08ffffbd-7e48-43d9-9423-d7a40b64a2ab' User entered '20 Aug 2020 18:42' | System | 20 Aug 2020 22:42:44 |
| | System | 20 Aug 2020 22:42:44 |

US3402284

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(13)

Generated On: 09 Jun 2021 17:25:19

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '20 Aug 2020 12:00' | System | 19 Aug 2020 01:09:27 |

US3402284

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(13)

Generated On: 09 Jun 2021 17:25:19

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '21 Aug 2020 11:59' | System | 19 Aug 2020 01:09:27 |

US3402284

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(14)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| Data entry locked. | System | 19 Aug 2020 22:52:53 |
| User entered 'Day 14' | System | 19 Aug 2020 22:52:53 |

US3402284

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(14)

Generated On: 09 Jun 2021 17:25:19

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-21T19:59:59', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '98e16756-cfe9-4918-b0c0-d8bec1647eee' User entered 'Some interference with activity (2)' | System | 22 Aug 2020 00:00:09 |
| | System | 22 Aug 2020 00:00:09 |

US3402284

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(14)

Generated On: 09 Jun 2021 17:25:19

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-21T20:00:03', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '98e16756-cfe9-4918-b0c0-d8bec1647eee' | System | 22 Aug 2020 00:00:09 |
| User entered '21 Aug 2020 20:00' | System | 22 Aug 2020 00:00:09 |

US3402284

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(14)

Generated On: 09 Jun 2021 17:25:19

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '21 Aug 2020 12:00' | System | 19 Aug 2020 22:52:53 |

US3402284

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(14)

Generated On: 09 Jun 2021 17:25:19

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '22 Aug 2020 11:59' | System | 19 Aug 2020 22:52:53 |

US3402284

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(15)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| Data entry locked. | System | 20 Aug 2020 22:42:44 |
| User entered 'Day 15' | System | 20 Aug 2020 22:42:44 |

US3402284

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(15)

Generated On: 09 Jun 2021 17:25:19

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-22T17:11:30', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'bb533f09-2403-4c7e-974b-1b2d080dcd02' | System | 22 Aug 2020 21:11:39 |
| User entered 'None (0)' | System | 22 Aug 2020 21:11:39 |

US3402284

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(15)

Generated On: 09 Jun 2021 17:25:19

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-22T17:11:34', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'bb533f09-2403-4c7e-974b-1b2d080dcd02' User entered '22 Aug 2020 17:11' | System | 22 Aug 2020 21:11:39 |
| | System | 22 Aug 2020 21:11:39 |

US3402284

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(15)

Generated On: 09 Jun 2021 17:25:19

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '22 Aug 2020 12:00' | System | 20 Aug 2020 22:42:44 |

US3402284

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(15)

Generated On: 09 Jun 2021 17:25:19

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '23 Aug 2020 11:59' | System | 20 Aug 2020 22:42:44 |

US3402284

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| Data entry locked. | System | 13 Aug 2020 23:50:13 |
| User entered 'Day 8' | System | 13 Aug 2020 23:50:13 |

US3402284

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 09 Jun 2021 17:25:19

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-15T22:50:01', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '8b2bdb2c-43a7-4383-9585-65410577095f' User entered 'No interference with activity (1)' | System | 16 Aug 2020 02:50:10 |
| | System | 16 Aug 2020 02:50:10 |

US3402284

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 09 Jun 2021 17:25:19

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-15T22:50:06', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '8b2bdb2c-43a7-4383-9585-65410577095f' User entered '15 Aug 2020 22:50' | System | 16 Aug 2020 02:50:10 |
| | System | 16 Aug 2020 02:50:10 |

US3402284

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 09 Jun 2021 17:25:19

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '15 Aug 2020 12:00' | System | 13 Aug 2020 23:50:13 |

US3402284

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 09 Jun 2021 17:25:19

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '16 Aug 2020 11:59' | System | 13 Aug 2020 23:50:13 |

US3402284

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| Data entry locked. | System | 15 Aug 2020 00:31:09 |
| User entered 'Day 9' | System | 15 Aug 2020 00:31:09 |

US3402284

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 09 Jun 2021 17:25:19

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-16T19:17:53', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '6ea44a54-5985-4940-bbd7-8fa9ddab00bd' User entered 'Some interference with activity (2)' | System | 16 Aug 2020 23:18:01 |
| | System | 16 Aug 2020 23:18:01 |

US3402284

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 09 Jun 2021 17:25:19

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-16T19:17:59', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '6ea44a54-5985-4940-bbd7-8fa9ddab00bd' User entered '16 Aug 2020 19:17' | System | 16 Aug 2020 23:18:01 |
| | System | 16 Aug 2020 23:18:01 |

US3402284

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 09 Jun 2021 17:25:19

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '16 Aug 2020 12:00' | System | 15 Aug 2020 00:31:09 |

US3402284

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 09 Jun 2021 17:25:19

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '17 Aug 2020 11:59' | System | 15 Aug 2020 00:31:09 |

US3402284

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(10)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| Data entry locked. | System | 16 Aug 2020 02:50:10 |
| User entered 'Day 10' | System | 16 Aug 2020 02:50:10 |

US3402284

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(10)

Generated On: 09 Jun 2021 17:25:19

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-17T17:48:16', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'bd1f2a08-a378-4968-88bf-479aa80826b5' | System | 17 Aug 2020 21:48:22 |
| User entered 'Some interference with activity (2)' | System | 17 Aug 2020 21:48:22 |

US3402284

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(10)

Generated On: 09 Jun 2021 17:25:19

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-17T17:48:20', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'bd1f2a08-a378-4968-88bf-479aa80826b5' User entered '17 Aug 2020 17:48' | System | 17 Aug 2020 21:48:22 |
| | System | 17 Aug 2020 21:48:22 |

US3402284

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(10)

Generated On: 09 Jun 2021 17:25:19

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '17 Aug 2020 12:00' | System | 16 Aug 2020 02:50:10 |

US3402284

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(10)

Generated On: 09 Jun 2021 17:25:19

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '18 Aug 2020 11:59' | System | 16 Aug 2020 02:50:10 |

US3402284

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(11)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| Data entry locked. | System | 16 Aug 2020 23:18:01 |
| User entered 'Day 11' | System | 16 Aug 2020 23:18:01 |

US3402284

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(11)

Generated On: 09 Jun 2021 17:25:19

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-18T21:09:31', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '64970c76-f9a0-4e99-a35e-86007b51d19b' | System | 19 Aug 2020 01:09:41 |
| User entered 'No interference with activity (1)' | System | 19 Aug 2020 01:09:41 |

US3402284

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(11)

Generated On: 09 Jun 2021 17:25:19

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-18T21:09:37', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '64970c76-f9a0-4e99-a35e-86007b51d19b' User entered '18 Aug 2020 21:09' | System | 19 Aug 2020 01:09:41 |
| | System | 19 Aug 2020 01:09:41 |

US3402284

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(11)

Generated On: 09 Jun 2021 17:25:19

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '18 Aug 2020 12:00' | System | 16 Aug 2020 23:18:01 |

US3402284

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(11)

Generated On: 09 Jun 2021 17:25:19

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '19 Aug 2020 11:59' | System | 16 Aug 2020 23:18:01 |

US3402284

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(12)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| Data entry locked. | System | 17 Aug 2020 21:48:22 |
| User entered 'Day 12' | System | 17 Aug 2020 21:48:22 |

US3402284

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(12)

Generated On: 09 Jun 2021 17:25:19

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-19T18:53:02', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '9a7e36a1-1b12-44bd-a7e6-4c1d8da433b6' | System | 19 Aug 2020 22:53:08 |
| User entered 'No interference with activity (1)' | System | 19 Aug 2020 22:53:08 |

US3402284

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(12)

Generated On: 09 Jun 2021 17:25:19

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-19T18:53:05', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '9a7e36a1-1b12-44bd-a7e6-4c1d8da433b6' User entered '19 Aug 2020 18:53' | System | 19 Aug 2020 22:53:08 |
| | System | 19 Aug 2020 22:53:08 |

US3402284

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(12)

Generated On: 09 Jun 2021 17:25:19

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '19 Aug 2020 12:00' | System | 17 Aug 2020 21:48:22 |

US3402284

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(12)

Generated On: 09 Jun 2021 17:25:19

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '20 Aug 2020 11:59' | System | 17 Aug 2020 21:48:22 |

US3402284

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(13)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| Data entry locked. | System | 19 Aug 2020 01:09:41 |
| User entered 'Day 13' | System | 19 Aug 2020 01:09:41 |

US3402284

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(13)

Generated On: 09 Jun 2021 17:25:19

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-20T18:42:51', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '13b43789-1959-457b-9ff5-f1d9131e3f5a' User entered 'None (0)' | System | 20 Aug 2020 22:42:59 |
| | System | 20 Aug 2020 22:42:59 |

US3402284

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(13)

Generated On: 09 Jun 2021 17:25:19

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-20T18:42:55', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '13b43789-1959-457b-9ff5-f1d9131e3f5a' User entered '20 Aug 2020 18:42' | System | 20 Aug 2020 22:42:59 |
| | System | 20 Aug 2020 22:42:59 |

US3402284

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(13)

Generated On: 09 Jun 2021 17:25:19

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '20 Aug 2020 12:00' | System | 19 Aug 2020 01:09:41 |

US3402284

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(13)

Generated On: 09 Jun 2021 17:25:19

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '21 Aug 2020 11:59' | System | 19 Aug 2020 01:09:41 |

US3402284

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| Data entry locked. | System | 13 Aug 2020 23:50:13 |
| User entered 'Day 8' | System | 13 Aug 2020 23:50:13 |

US3402284

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-15T22:50:34', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'f65a4c69-c580-44fe-8e3c-1a286274fb54' | System | 16 Aug 2020 02:50:41 |
| User entered 'No (N)' | System | 16 Aug 2020 02:50:41 |

US3402284

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:25:19

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-15T22:50:39', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'f65a4c69-c580-44fe-8e3c-1a286274fb54' | System | 16 Aug 2020 02:50:41 |
| User entered '15 Aug 2020 22:50' | System | 16 Aug 2020 02:50:41 |

US3402284

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:25:19

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '15 Aug 2020 12:00' | System | 13 Aug 2020 23:50:13 |

US3402284

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:25:19

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '16 Aug 2020 11:59' | System | 13 Aug 2020 23:50:13 |

US3402284

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| Data entry locked. | System | 15 Aug 2020 00:31:09 |
| User entered 'Day 9' | System | 15 Aug 2020 00:31:09 |

US3402284

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-16T19:18:08', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '9dd4c99e-b157-44a6-9df2-41a013140346' User entered 'No (N)' | System | 16 Aug 2020 23:18:13 |
| | System | 16 Aug 2020 23:18:13 |

US3402284

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 17:25:19

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-16T19:18:11', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '9dd4c99e-b157-44a6-9df2-41a013140346' User entered '16 Aug 2020 19:18' | System | 16 Aug 2020 23:18:13 |
| | System | 16 Aug 2020 23:18:13 |

US3402284

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 17:25:19

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '16 Aug 2020 12:00' | System | 15 Aug 2020 00:31:09 |

US3402284

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 17:25:19

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '17 Aug 2020 11:59' | System | 15 Aug 2020 00:31:09 |

US3402284

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| Data entry locked. | System | 16 Aug 2020 02:49:37 |
| User entered 'Day 10' | System | 16 Aug 2020 02:49:37 |

US3402284

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-17T17:47:58', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'fbd487e1-98b0-41ae-ae89-3dc8db7e3869' User entered 'No (N)' | System | 17 Aug 2020 21:48:05 |
| | System | 17 Aug 2020 21:48:05 |

US3402284

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 17:25:19

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-17T17:48:03', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'fbd487e1-98b0-41ae-ae89-3dc8db7e3869' | System | 17 Aug 2020 21:48:05 |
| User entered '17 Aug 2020 17:48' | System | 17 Aug 2020 21:48:05 |

US3402284

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 17:25:19

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '17 Aug 2020 12:00' | System | 16 Aug 2020 02:49:37 |

US3402284

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 17:25:19

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '18 Aug 2020 11:59' | System | 16 Aug 2020 02:49:37 |

US3402284

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| Data entry locked. | System | 16 Aug 2020 23:17:25 |
| User entered 'Day 11' | System | 16 Aug 2020 23:17:25 |

US3402284

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-18T21:09:46', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '100785ff-8b74-42ee-a50a-1953d71cca14' | System | 19 Aug 2020 01:09:51 |
| User entered 'No (N)' | System | 19 Aug 2020 01:09:51 |

US3402284

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 17:25:19

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-18T21:09:49', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '100785ff-8b74-42ee-a50a-1953d71cca14' User entered '18 Aug 2020 21:09' | System | 19 Aug 2020 01:09:51 |
| | System | 19 Aug 2020 01:09:51 |

US3402284

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 17:25:19

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '18 Aug 2020 12:00' | System | 16 Aug 2020 23:17:25 |

US3402284

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 17:25:19

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '19 Aug 2020 11:59' | System | 16 Aug 2020 23:17:25 |

US3402284

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| Data entry locked. | System | 17 Aug 2020 21:47:52 |
| User entered 'Day 12' | System | 17 Aug 2020 21:47:52 |

US3402284

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-19T18:53:12', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '11ae3dbc-d387-47a5-8dc2-8c324f87023e' User entered 'No (N)' | System | 19 Aug 2020 22:53:19 |
| | System | 19 Aug 2020 22:53:19 |

US3402284

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 09 Jun 2021 17:25:19

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-19T18:53:17', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '11ae3dbc-d387-47a5-8dc2-8c324f87023e' User entered '19 Aug 2020 18:53' | System | 19 Aug 2020 22:53:19 |
| | System | 19 Aug 2020 22:53:19 |

US3402284

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 09 Jun 2021 17:25:19

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '19 Aug 2020 12:00' | System | 17 Aug 2020 21:47:52 |

US3402284

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 09 Jun 2021 17:25:19

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '20 Aug 2020 11:59' | System | 17 Aug 2020 21:47:52 |

US3402284

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| Data entry locked. | System | 19 Aug 2020 01:09:13 |
| User entered 'Day 13' | System | 19 Aug 2020 01:09:13 |

US3402284

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-20T18:43:02', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '48f2fc3e-d94a-49b8-98fb-d529a8c19fb5' User entered 'No (N)' | System | 20 Aug 2020 22:43:10 |
| | System | 20 Aug 2020 22:43:10 |

US3402284

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 09 Jun 2021 17:25:19

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-20T18:43:08', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '48f2fc3e-d94a-49b8-98fb-d529a8c19fb5' User entered '20 Aug 2020 18:43' | System | 20 Aug 2020 22:43:10 |
| | System | 20 Aug 2020 22:43:10 |

US3402284

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 09 Jun 2021 17:25:19

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '20 Aug 2020 12:00' | System | 19 Aug 2020 01:09:13 |

US3402284

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 09 Jun 2021 17:25:19

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '21 Aug 2020 11:59' | System | 19 Aug 2020 01:09:13 |

US3402284

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| Data entry locked. | System | 19 Aug 2020 22:52:36 |
| User entered 'Day 14' | System | 19 Aug 2020 22:52:36 |

US3402284

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-21T20:00:10', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '0e8ace33-8de4-4d1b-81fb-a8304b3c8c58' | System | 22 Aug 2020 00:00:16 |
| User entered 'No (N)' | System | 22 Aug 2020 00:00:16 |

US3402284

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 09 Jun 2021 17:25:19

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-21T20:00:13', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '0e8ace33-8de4-4d1b-81fb-a8304b3c8c58' | System | 22 Aug 2020 00:00:16 |
| User entered '21 Aug 2020 20:00' | System | 22 Aug 2020 00:00:16 |

US3402284

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 09 Jun 2021 17:25:19

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '21 Aug 2020 12:00' | System | 19 Aug 2020 22:52:36 |

US3402284

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 09 Jun 2021 17:25:19

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '22 Aug 2020 11:59' | System | 19 Aug 2020 22:52:36 |

US3402284

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| Data entry locked. | System | 20 Aug 2020 22:42:31 |
| User entered 'Day 15' | System | 20 Aug 2020 22:42:31 |

US3402284

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-22T17:11:41', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'bb5cf396-c67e-4ba4-bae8-98f0a752d436' | System | 22 Aug 2020 21:11:46 |
| User entered 'No (N)' | System | 22 Aug 2020 21:11:46 |

US3402284

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 09 Jun 2021 17:25:19

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-08-22T17:11:44', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'bb5cf396-c67e-4ba4-bae8-98f0a752d436' | System | 22 Aug 2020 21:11:46 |
| User entered '22 Aug 2020 17:11' | System | 22 Aug 2020 21:11:46 |

US3402284

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 09 Jun 2021 17:25:19

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '22 Aug 2020 12:00' | System | 20 Aug 2020 22:42:31 |

US3402284

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 09 Jun 2021 17:25:19

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '23 Aug 2020 11:59' | System | 20 Aug 2020 22:42:31 |

US3402284

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:25:19

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered 'Yes (Y)' | (b) (4) Traci Hull (b) (4) | 24 Aug 2020 18:08:31 |

US3402284

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:25:19

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered '15 Aug 2020' | (b) (4) Traci Hull (b) (4) (b) (4) | 24 Aug 2020 18:08:31 |

US3402284

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:25:19

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered 'Contact Made (CONTACT MADE)' | Traci Hull (b) (4) | 24 Aug 2020 18:08:31 |

US3402284

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:25:19

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered empty. | Traci Hull (b) (4) | 24 Aug 2020 18:08:31 |

US3402284

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:25:19

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered 'Yes (Y)' | (b) (4) Traci Hull (b) (4) (b) (4) | 24 Aug 2020 18:08:36 |

US3402284

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:25:19

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User entered 'I' | System | 24 Aug 2020 18:08:36 |

US3402284

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:25:19

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User closed query 'Was Contact Attempted? = Yes and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is missing. Please review and reconcile.' (Site from System). | (b) (4) | |
| User opened query 'Was Contact Attempted? = Yes and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is missing. Please review and reconcile.' (Site from System). | System | 24 Aug 2020 18:09:05 |
| User entered 'Yes (Y)' | System | 24 Aug 2020 18:08:54 |
| | Traci Hull (b) (4) | 24 Aug 2020 18:08:54 |
| | (b) (4) | |

US3402284

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:25:19

Date of Contact or Contact Attempt (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered '22 Aug 2020' reason for change: Data Entry Error | Traci Hull (b) (4) | 24 Aug 2020 18:09:05 |
| User entered empty. | Traci Hull (b) (4) | 24 Aug 2020 18:08:54 |

US3402284

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:25:19

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered 'Contact Made (CONTACT MADE)' | Traci Hull (b) (4) | 24 Aug 2020 18:08:54 |

US3402284

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:25:19

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered empty. | Traci Hull (b) (4) | 24 Aug 2020 18:08:54 |

US3402284

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:25:19

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered 'Yes (Y)' | Traci Hull (b) (4) | 24 Aug 2020 18:09:14 |

US3402284

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:25:19

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User entered 'I' | System | 24 Aug 2020 18:09:14 |

US3402284

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:25:19

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered 'Yes (Y)' | (b) (4) Traci Hull (b) (4) | 29 Aug 2020 15:47:45 |

US3402284

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:25:19

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered '29 Aug 2020' | Traci Hull (b) (4) | 29 Aug 2020 15:47:45 |

US3402284

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:25:19

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered 'Contact Made (CONTACT MADE)' | Traci Hull (b) (4) | 29 Aug 2020 15:47:45 |

US3402284

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:25:19

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered empty. | (b) (4) | |
| | Traci Hull (b) (4) | 29 Aug 2020 15:47:45 |
| | (b) (4) | |

US3402284

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:25:19

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered 'Yes (Y)' | (b) (4) Traci Hull (b) (4) (b) (4) | 29 Aug 2020 15:47:50 |

US3402284

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:25:19

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User entered 'I' | System | 29 Aug 2020 15:47:50 |

US3402284

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:25:19

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered 'Yes (Y)' | (b) (4) Traci Hull (b) (4) (b) (4) | 10 Sep 2020 21:06:15 |

US3402284

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered '10 Sep 2020' | (b) (4) Traci Hull (b) (4) (b) (4) | 10 Sep 2020 21:06:15 |

US3402284

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|--------------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered 'Clinic (Clinic)' | Traci Hull (b) (4) | 10 Sep 2020 21:06:15 |

US3402284

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:25:19

[Folder OID](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User entered 'VISIT2' | System | 10 Sep 2020 21:06:15 |

US3402284

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:25:19

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User accepted default value 'Pre-Dose (PREDOSE)' | Traci Hull (b) (4) (b) (4) | 10 Sep 2020 21:09:27 |

US3402284

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:25:19

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered 'Yes (Y)' | (b) (4) Traci Hull (b) (4) (b) (4) | 10 Sep 2020 21:09:27 |

US3402284

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:25:19

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered '10 Sep 2020' | Traci Hull (b) (4) | 10 Sep 2020 21:09:27 |

US3402284

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered '15:36' | (b) (4) Traci Hull (b) (4) (b) (4) | 10 Sep 2020 21:09:27 |

US3402284

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User entered '10 Sep 2020 15:36' | System | 10 Sep 2020 21:09:27 |

US3402284

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:25:19

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered '36.5' C | (b) (4) | |
| | Traci Hull (b) (4) | 10 Sep 2020 21:09:27 |
| | (b) (4) | |

US3402284

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:25:19

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered 'Oral (Oral)' | (b) (4) Traci Hull (b) (4) (b) (4) | 10 Sep 2020 21:09:27 |

US3402284

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:25:19

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered empty. | (b) (4) Traci Hull (b) (4) (b) (4) | 10 Sep 2020 21:09:27 |

US3402284

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:25:19

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered '91' | (b) (4) Traci Hull (b) (4) | 10 Sep 2020 21:09:27 |

US3402284

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:25:19

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User entered 'bpm' | System | 10 Sep 2020 21:09:27 |

US3402284

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered '15' | (b) (4) Traci Hull (b) (4) | 10 Sep 2020 21:09:27 |

US3402284

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:25:19

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User entered 'breaths/min' | System | 10 Sep 2020 21:09:27 |

US3402284

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered '138' | (b) (4) Traci Hull (b) (4) (b) (4) | 10 Sep 2020 21:09:27 |

US3402284

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:25:19

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User entered 'mmHg' | System | 10 Sep 2020 21:09:27 |

US3402284

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered '87' | (b) (4) Traci Hull (b) (4) | 10 Sep 2020 21:09:27 |

US3402284

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:25:19

Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User entered 'mmHg' | System | 10 Sep 2020 21:09:27 |

US3402284

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:25:19

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User accepted default value 'Post-Dose (POSTDOSE)' | Traci Hull (b) (4) (b) (4) | 10 Sep 2020 21:09:27 |

US3402284

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:25:19

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered 'Yes (Y)' | (b) (4) Traci Hull (b) (4) | 10 Sep 2020 21:09:27 |

US3402284

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:25:19

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered '10 Sep 2020' | (b) (4) Traci Hull (b) (4) (b) (4) | 10 Sep 2020 21:09:27 |

US3402284

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered '16:50' | (b) (4) Traci Hull (b) (4) (b) (4) | 10 Sep 2020 21:09:27 |

US3402284

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User entered '10 Sep 2020 16:50' | System | 10 Sep 2020 21:09:27 |

US3402284

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:25:19

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered '36.8' C | (b) (4) | |
| | Traci Hull (b) (4) | 10 Sep 2020 21:09:27 |
| | (b) (4) | |

US3402284

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:25:19

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered 'Oral (Oral)' | (b) (4) Traci Hull (b) (4) (b) (4) | 10 Sep 2020 21:09:27 |

US3402284

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:25:19

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered empty. | (b) (4) Traci Hull (b) (4) | 10 Sep 2020 21:09:27 |

US3402284

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:25:19

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered '87' | (b) (4) Traci Hull (b) (4) | 10 Sep 2020 21:09:27 |

US3402284

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:25:19

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User entered 'bpm' | System | 10 Sep 2020 21:09:27 |

US3402284

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered '15' | (b) (4) Traci Hull (b) (4) | 10 Sep 2020 21:09:27 |

US3402284

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:25:19

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User entered 'breaths/min' | System | 10 Sep 2020 21:09:27 |

US3402284

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:25:19

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered '126' | (b) (4) | |
| | Traci Hull (b) (4) | 10 Sep 2020 21:09:27 |
| | (b) (4) | |

US3402284

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:25:19

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User entered 'mmHg' | System | 10 Sep 2020 21:09:27 |

US3402284

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered '80' | (b) (4) Traci Hull (b) (4) (b) (4) | 10 Sep 2020 21:09:27 |

US3402284

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:25:19

Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User entered 'mmHg' | System | 10 Sep 2020 21:09:27 |

US3402284

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:25:19

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered 'Yes (Y)' | Traci Hull (b) (4) | 10 Sep 2020 21:09:33 |

US3402284

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:25:19

Date of examination (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered '10 Sep 2020' | Traci Hull (b) (4) | 10 Sep 2020 21:09:33 |

US3402284

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:25:19

[Was study treatment given?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered 'Yes (Y)' | (b) (4) Abigail Wine (b) (4) | 10 Sep 2020 20:20:29 |

US3402284

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:25:19

[If No, reason not given](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered empty. | (b) (4) Abigail Wine (b) (4) | 10 Sep 2020 20:20:29 |

US3402284

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:25:19

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) | 27 Mar 2021 18:53:35 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered empty. | Abigail Wine (b) (4) | 10 Sep 2020 20:20:29 |

US3402284

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:25:19

[What was the study treatment?](#)

| Audit | User | Time (GMT) |
|-------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User entered 'MRNA-1273 OR PLACEBO' | System | 10 Sep 2020 20:20:29 |

US3402284

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:25:19

What was the treatment date? (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered '10 Sep 2020' | Abigail Wine (b) (4) | 10 Sep 2020 20:20:29 |

US3402284

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered '16:17' | (b) (4) Abigail Wine (b) (4) | 10 Sep 2020 20:20:29 |

US3402284

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User entered '10 Sep 2020 16:17' | System | 10 Sep 2020 20:20:29 |

US3402284

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|------------------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered 'Left Arm (LEFT ARM)' | Abigail Wine (b) (4) | 10 Sep 2020 20:20:29 |

US3402284

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User entered 'ONCE' | System | 10 Sep 2020 20:20:29 |

US3402284

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:25:19

What was the route of administration for the study treatment?

| Audit | User | Time (GMT) |
|------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User entered 'INTRAMUSCULAR' | System | 10 Sep 2020 20:20:29 |

US3402284

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:25:19

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered 'Yes (Y)' | (b) (4) Traci Hull (b) (4) | 10 Sep 2020 21:09:53 |

US3402284

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:25:19

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered '10 Sep 2020' | (b) (4) Traci Hull (b) (4) | 10 Sep 2020 21:09:53 |

US3402284

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:25:19

[Collection time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered '15:52' | (b) (4) Traci Hull (b) (4) | 10 Sep 2020 21:09:53 |

US3402284

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User entered '10 Sep 2020 15:52' | System | 10 Sep 2020 21:09:53 |

US3402284

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:25:19

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered '10 Sep 2020' | Traci Hull (b) (4) | 10 Sep 2020 21:10:09 |

US3402284

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:25:19

[Lab Test](#)

| Audit | User | Time (GMT) |
|--|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)' | Traci Hull (b) (4) (b) (4) | 10 Sep 2020 21:10:09 |

US3402284

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:25:19

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered 'Yes (Y)' | (b) (4) Traci Hull (b) (4) (b) (4) | 10 Sep 2020 21:10:09 |

US3402284

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:25:19

[Collection time \(00:00 - 23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered '15:55' | (b) (4) Traci Hull (b) (4) (b) (4) | 10 Sep 2020 21:10:09 |

US3402284

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User entered '10 Sep 2020 15:55' | System | 10 Sep 2020 21:10:09 |

US3402284

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:25:19

[Lab Test](#)

| Audit | User | Time (GMT) |
|--|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)' | Traci Hull (b) (4) (b) (4) | 10 Sep 2020 21:10:09 |

US3402284

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:25:19

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered 'No (N)' | (b) (4) Traci Hull (b) (4) (b) (4) | 10 Sep 2020 21:10:09 |

US3402284

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:25:19

[Collection time \(00:00 - 23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered empty. | (b) (4) Traci Hull (b) (4) (b) (4) | 10 Sep 2020 21:10:09 |

US3402284

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User entered empty. | System | 10 Sep 2020 21:10:09 |

US3402284

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:25:19

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered 'Yes (Y)' | Traci Hull (b) (4) | 10 Sep 2020 21:10:13 |

US3402284

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:25:19

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User entered 'I' | System | 10 Sep 2020 21:10:13 |

US3402284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| Data entry locked. | System | 10 Sep 2020 20:20:29 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 10 Sep 2020 20:20:29 |

US3402284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:25:19

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-10T16:51:34', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '6770faa5-a633-4908-b2ad-792dada40d07' User entered 'Yes (Y)' | System | 10 Sep 2020 20:52:22 |
| | System | 10 Sep 2020 20:52:22 |

US3402284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:25:19

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-10T16:51:59', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '6770faa5-a633-4908-b2ad-792dada40d07' User entered '98.2' | System | 10 Sep 2020 20:52:22 |
| | System | 10 Sep 2020 20:52:22 |

US3402284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-10T16:52:06', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '6770faa5-a633-4908-b2ad-792dada40d07' | System | 10 Sep 2020 20:52:22 |
| User entered 'No (N)' | System | 10 Sep 2020 20:52:22 |

US3402284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:25:19

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-10T16:52:18', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '6770faa5-a633-4908-b2ad-792dada40d07' User entered '10 Sep 2020 16:52' | System | 10 Sep 2020 20:52:22 |
| | System | 10 Sep 2020 20:52:22 |

US3402284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:25:19

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '10 Sep 2020 16:37' | System | 10 Sep 2020 20:20:29 |

US3402284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:25:19

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '10 Sep 2020 19:07' | System | 10 Sep 2020 20:20:29 |

US3402284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| Data entry locked. | System | 10 Sep 2020 20:20:29 |
| User entered 'Day 1, after vaccination (at home)' | System | 10 Sep 2020 20:20:29 |

US3402284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:25:19

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-10T21:29:02', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '0da8c531-583d-4f82-b4f1-7462fba11e6d' User entered 'Yes (Y)' | System | 11 Sep 2020 01:29:45 |
| | System | 11 Sep 2020 01:29:45 |

US3402284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:25:19

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-10T21:29:11', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '0da8c531-583d-4f82-b4f1-7462fba11e6d' User entered '98.2' | System | 11 Sep 2020 01:29:45 |
| | System | 11 Sep 2020 01:29:45 |

US3402284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-10T21:29:30', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '0da8c531-583d-4f82-b4f1-7462fba11e6d' User entered 'No (N)' | System | 11 Sep 2020 01:29:45 |
| | System | 11 Sep 2020 01:29:45 |

US3402284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:25:19

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-10T21:29:41', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '0da8c531-583d-4f82-b4f1-7462fba11e6d' User entered '10 Sep 2020 21:29' | System | 11 Sep 2020 01:29:45 |
| | System | 11 Sep 2020 01:29:45 |

US3402284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:25:19

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '10 Sep 2020 20:02' | System | 10 Sep 2020 20:20:29 |

US3402284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:25:19

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '11 Sep 2020 11:59' | System | 10 Sep 2020 20:20:29 |

US3402284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| Data entry locked. | System | 10 Sep 2020 20:20:29 |
| User entered 'Day 2' | System | 10 Sep 2020 20:20:29 |

US3402284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:25:19

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-11T19:53:31', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '682f6c0b-7d7f-4f20-bc3d-7dc848cd889d' User entered 'Yes (Y)' | System | 11 Sep 2020 23:53:56 |
| | System | 11 Sep 2020 23:53:56 |

US3402284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:25:19

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-11T19:53:41', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '682f6c0b-7d7f-4f20-bc3d-7dc848cd889d' User entered '97.7' | System | 11 Sep 2020 23:53:56 |
| | System | 11 Sep 2020 23:53:56 |

US3402284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-11T19:53:48', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '682f6c0b-7d7f-4f20-bc3d-7dc848cd889d' User entered 'No (N)' | System | 11 Sep 2020 23:53:56 |
| | System | 11 Sep 2020 23:53:56 |

US3402284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:25:19

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-11T19:53:52', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '682f6c0b-7d7f-4f20-bc3d-7dc848cd889d' User entered '11 Sep 2020 19:53' | System | 11 Sep 2020 23:53:56 |
| | System | 11 Sep 2020 23:53:56 |

US3402284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:25:19

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '11 Sep 2020 12:00' | System | 10 Sep 2020 20:20:29 |

US3402284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:25:19

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '12 Sep 2020 11:59' | System | 10 Sep 2020 20:20:29 |

US3402284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| Data entry locked. | System | 10 Sep 2020 20:20:29 |
| User entered 'Day 3' | System | 10 Sep 2020 20:20:29 |

US3402284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:25:19

Was TEMPERATURE taken?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-12T19:07:30', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '152c84ad-c5ef-4823-8652-716f0beffb88' User entered 'Yes (Y)' | System | 12 Sep 2020 23:08:11 |
| | System | 12 Sep 2020 23:08:11 |

US3402284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:25:19

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-12T19:07:38', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '152c84ad-c5ef-4823-8652-716f0beffb88' User entered '98.7' | System | 12 Sep 2020 23:08:11 |
| | System | 12 Sep 2020 23:08:11 |

US3402284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-12T19:07:45', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '152c84ad-c5ef-4823-8652-716f0beffb88' | System | 12 Sep 2020 23:08:11 |
| User entered 'No (N)' | System | 12 Sep 2020 23:08:11 |

US3402284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:25:19

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-12T19:07:49', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '152c84ad-c5ef-4823-8652-716f0beffb88' User entered '12 Sep 2020 19:07' | System | 12 Sep 2020 23:08:11 |
| | System | 12 Sep 2020 23:08:11 |

US3402284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:25:19

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '12 Sep 2020 12:00' | System | 10 Sep 2020 20:20:29 |

US3402284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:25:19

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '13 Sep 2020 11:59' | System | 10 Sep 2020 20:20:29 |

US3402284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| Data entry locked. | System | 10 Sep 2020 20:20:29 |
| User entered 'Day 4' | System | 10 Sep 2020 20:20:29 |

US3402284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:25:19

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-13T20:32:21', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'ef676004-45e6-4cde-a1fd-a2edb09606f3' User entered 'Yes (Y)' | System | 14 Sep 2020 00:32:33 |
| | System | 14 Sep 2020 00:32:33 |

US3402284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:25:19

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-13T20:32:05', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'ef676004-45e6-4cde-a1fd-a2edb09606f3' User entered '98.8' | System | 14 Sep 2020 00:32:33 |
| | System | 14 Sep 2020 00:32:33 |

US3402284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-13T20:32:12', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'ef676004-45e6-4cde-a1fd-a2edb09606f3' | System | 14 Sep 2020 00:32:33 |
| User entered 'No (N)' | System | 14 Sep 2020 00:32:33 |

US3402284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:25:19

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-13T20:32:29', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'ef676004-45e6-4cde-a1fd-a2edb09606f3' User entered '13 Sep 2020 20:32' | System | 14 Sep 2020 00:32:33 |
| | System | 14 Sep 2020 00:32:33 |

US3402284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:25:19

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '13 Sep 2020 12:00' | System | 10 Sep 2020 20:20:29 |

US3402284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:25:19

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '14 Sep 2020 11:59' | System | 10 Sep 2020 20:20:29 |

US3402284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| Data entry locked. | System | 10 Sep 2020 20:20:29 |
| User entered 'Day 5' | System | 10 Sep 2020 20:20:29 |

US3402284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:25:19

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-14T19:52:34', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'a3359203-fabb-4e9c-a406-3a71282d2446' User entered 'Yes (Y)' | System | 14 Sep 2020 23:53:17 |
| | System | 14 Sep 2020 23:53:17 |

US3402284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:25:19

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-14T19:52:49', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'a3359203-fabb-4e9c-a406-3a71282d2446' User entered '98.4' | System | 14 Sep 2020 23:53:17 |

US3402284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-14T19:52:56', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'a3359203-fabb-4e9c-a406-3a71282d2446' | System | 14 Sep 2020 23:53:17 |
| User entered 'Yes (Y)' | System | 14 Sep 2020 23:53:17 |

US3402284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|---|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'MILD FATIGUE, MUSCLE ACCHEs' (Site from System). | (b) (4), (b) (6) | 30 Sep 2020 11:21:41 |
| Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'MILD FATIGUE, MUSCLE ACCHEs' (Site from System). | Tammy Kohn (b) (4) (b) (4) | 26 Sep 2020 15:14:35 |
| User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). | System | 14 Sep 2020 23:53:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-14T19:53:08', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'a3359203-fabb-4e9c-a406-3a71282d2446' | System | 14 Sep 2020 23:53:17 |
| User entered '1' | System | 14 Sep 2020 23:53:17 |

US3402284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:25:19

To **PREVENT** pain or fever from occurring

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-14T19:53:08', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'a3359203-fabb-4e9c-a406-3a71282d2446' User entered '0' | System | 14 Sep 2020 23:53:17 |

US3402284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:25:19

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-14T19:53:15', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'a3359203-fabb-4e9c-a406-3a71282d2446' User entered '14 Sep 2020 19:53' | System | 14 Sep 2020 23:53:17 |
| | System | 14 Sep 2020 23:53:17 |

US3402284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:25:19

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '14 Sep 2020 12:00' | System | 10 Sep 2020 20:20:29 |

US3402284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:25:19

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '15 Sep 2020 11:59' | System | 10 Sep 2020 20:20:29 |

US3402284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| Data entry locked. | System | 10 Sep 2020 20:20:29 |
| User entered 'Day 6' | System | 10 Sep 2020 20:20:29 |

US3402284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:25:19

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-15T19:32:47', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '25329765-d454-4f66-8dec-4e9f16519a7a' User entered 'Yes (Y)' | System | 15 Sep 2020 23:33:26 |
| | System | 15 Sep 2020 23:33:26 |

US3402284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:25:19

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-15T19:32:57', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '25329765-d454-4f66-8dec-4e9f16519a7a' User entered '97.6' | System | 15 Sep 2020 23:33:26 |
| | System | 15 Sep 2020 23:33:26 |

US3402284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-15T19:33:03', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '25329765-d454-4f66-8dec-4e9f16519a7a' User entered 'Yes (Y)' | System | 15 Sep 2020 23:33:26 |
| | System | 15 Sep 2020 23:33:26 |

US3402284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|---|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'MILD FATIGUE, MUSCLE ACHES AND JOINT PAIN' (Site from System). | (b) (4), (b) (6) | 30 Sep 2020 11:21:30 |
| User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). | Tammy Kohn (b) (4) | 26 Sep 2020 15:15:05 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-15T19:33:17', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '25329765-d454-4f66-8dec-4e9f16519a7a' | (b) (4) | |
| User entered '1' | System | 15 Sep 2020 23:33:26 |
| | System | 15 Sep 2020 23:33:26 |
| | System | 15 Sep 2020 23:33:26 |

US3402284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:25:19

To **PREVENT** pain or fever from occurring

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-15T19:33:17', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '25329765-d454-4f66-8dec-4e9f16519a7a' User entered '0' | System | 15 Sep 2020 23:33:26 |
| | System | 15 Sep 2020 23:33:26 |

US3402284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:25:19

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-15T19:33:23', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '25329765-d454-4f66-8dec-4e9f16519a7a' User entered '15 Sep 2020 19:33' | System | 15 Sep 2020 23:33:26 |
| | System | 15 Sep 2020 23:33:26 |

US3402284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:25:19

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '15 Sep 2020 12:00' | System | 10 Sep 2020 20:20:29 |

US3402284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:25:19

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '16 Sep 2020 11:59' | System | 10 Sep 2020 20:20:29 |

US3402284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| Data entry locked. | System | 10 Sep 2020 20:20:29 |
| User entered 'Day 7' | System | 10 Sep 2020 20:20:29 |

US3402284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:25:19

Was TEMPERATURE taken?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-16T20:03:56', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'f8e0cb44-3a28-4d8c-be04-5e48a1c02cda' User entered 'Yes (Y)' | System | 17 Sep 2020 00:04:18 |
| | System | 17 Sep 2020 00:04:18 |

US3402284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:25:19

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-16T20:04:04', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'f8e0cb44-3a28-4d8c-be04-5e48a1c02cda' User entered '97.6' | System | 17 Sep 2020 00:04:18 |
| | System | 17 Sep 2020 00:04:18 |

US3402284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-16T20:04:10', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'f8e0cb44-3a28-4d8c-be04-5e48a1c02cda' User entered 'No (N)' | System | 17 Sep 2020 00:04:18 |
| | System | 17 Sep 2020 00:04:18 |

US3402284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:25:19

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-16T20:04:15', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'f8e0cb44-3a28-4d8c-be04-5e48a1c02cda' User entered '16 Sep 2020 20:04' | System | 17 Sep 2020 00:04:18 |
| | System | 17 Sep 2020 00:04:18 |

US3402284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:25:19

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '16 Sep 2020 12:00' | System | 10 Sep 2020 20:20:29 |

US3402284

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:25:19

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '17 Sep 2020 11:59' | System | 10 Sep 2020 20:20:29 |

US3402284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| Data entry locked. | System | 10 Sep 2020 20:20:29 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 10 Sep 2020 20:20:29 |

US3402284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:25:19

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-10T16:52:34', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '84860adb-da16-41e4-94e2-7804756f10d1' User entered 'Does not interfere with activity (2)' | System | 10 Sep 2020 20:53:20 |
| | System | 10 Sep 2020 20:53:20 |

US3402284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:25:19

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-10T16:53:02', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '84860adb-da16-41e4-94e2-7804756f10d1' User entered 'No (N)' | System | 10 Sep 2020 20:53:20 |
| | System | 10 Sep 2020 20:53:20 |

US3402284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-10T16:53:06', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '84860adb-da16-41e4-94e2-7804756f10d1' User entered 'No (N)' | System | 10 Sep 2020 20:53:20 |
| | System | 10 Sep 2020 20:53:20 |

US3402284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:25:19

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-10T16:53:15', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '84860adb-da16-41e4-94e2-7804756f10d1' | System | 10 Sep 2020 20:53:20 |
| User entered 'None (1)' | System | 10 Sep 2020 20:53:20 |

US3402284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:25:19

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-10T16:53:19', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '84860adb-da16-41e4-94e2-7804756f10d1' User entered '10 Sep 2020 16:53' | System | 10 Sep 2020 20:53:20 |
| | System | 10 Sep 2020 20:53:20 |

US3402284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:25:19

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '10 Sep 2020 16:37' | System | 10 Sep 2020 20:20:29 |

US3402284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:25:19

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '10 Sep 2020 19:07' | System | 10 Sep 2020 20:20:29 |

US3402284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| Data entry locked. | System | 10 Sep 2020 20:20:29 |
| User entered 'Day 1, after vaccination (at home)' | System | 10 Sep 2020 20:20:29 |

US3402284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:25:19

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-10T21:29:52', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '80f168d0-9c15-43e8-8b45-aa3021e573e0' | System | 11 Sep 2020 01:30:21 |
| User entered 'Does not interfere with activity (2)' | System | 11 Sep 2020 01:30:21 |

US3402284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-10T21:29:56', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '80f168d0-9c15-43e8-8b45-aa3021e573e0' User entered 'No (N)' | System | 11 Sep 2020 01:30:21 |
| | System | 11 Sep 2020 01:30:21 |

US3402284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-10T21:30:01', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '80f168d0-9c15-43e8-8b45-aa3021e573e0' User entered 'No (N)' | System | 11 Sep 2020 01:30:21 |
| | System | 11 Sep 2020 01:30:21 |

US3402284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:25:19

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-10T21:30:13', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '80f168d0-9c15-43e8-8b45-aa3021e573e0' User entered 'None (1)' | System | 11 Sep 2020 01:30:21 |
| | System | 11 Sep 2020 01:30:21 |

US3402284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:25:19

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-10T21:30:16', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '80f168d0-9c15-43e8-8b45-aa3021e573e0' User entered '10 Sep 2020 21:30' | System | 11 Sep 2020 01:30:21 |
| | System | 11 Sep 2020 01:30:21 |

US3402284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:25:19

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '10 Sep 2020 20:02' | System | 10 Sep 2020 20:20:29 |

US3402284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:25:19

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '11 Sep 2020 11:59' | System | 10 Sep 2020 20:20:29 |

US3402284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| Data entry locked. | System | 10 Sep 2020 20:20:29 |
| User entered 'Day 2' | System | 10 Sep 2020 20:20:29 |

US3402284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:25:19

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-11T19:54:00', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '54d4e31a-e951-4b64-aff8-cacfc993284b' User entered 'Does not interfere with activity (2)' | System | 11 Sep 2020 23:54:26 |
| | | |
| | System | 11 Sep 2020 23:54:26 |

US3402284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:25:19

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-11T19:54:05', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '54d4e31a-e951-4b64-aff8-cacfc993284b' User entered 'No (N)' | System | 11 Sep 2020 23:54:26 |
| | System | 11 Sep 2020 23:54:26 |

US3402284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-11T19:54:14', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '54d4e31a-e951-4b64-aff8-cacfc993284b' User entered 'No (N)' | System | 11 Sep 2020 23:54:26 |
| | System | 11 Sep 2020 23:54:26 |

US3402284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:25:19

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-11T19:54:21', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '54d4e31a-e951-4b64-aff8-cacfc993284b' User entered 'None (1)' | System | 11 Sep 2020 23:54:26 |
| | System | 11 Sep 2020 23:54:26 |

US3402284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:25:19

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-11T19:54:24', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '54d4e31a-e951-4b64-aff8-cacfc993284b' User entered '11 Sep 2020 19:54' | System | 11 Sep 2020 23:54:26 |
| | System | 11 Sep 2020 23:54:26 |

US3402284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:25:19

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '11 Sep 2020 12:00' | System | 10 Sep 2020 20:20:29 |

US3402284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:25:19

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '12 Sep 2020 11:59' | System | 10 Sep 2020 20:20:29 |

US3402284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| Data entry locked. | System | 10 Sep 2020 20:20:29 |
| User entered 'Day 3' | System | 10 Sep 2020 20:20:29 |

US3402284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:25:19

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-12T19:07:58', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '58f80690-c108-4d9c-98d0-681f5583f1ba' User entered 'Does not interfere with activity (2)' | System | 12 Sep 2020 23:08:36 |
| | System | 12 Sep 2020 23:08:36 |

US3402284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:25:19

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-12T19:08:04', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '58f80690-c108-4d9c-98d0-681f5583f1ba' User entered 'No (N)' | System | 12 Sep 2020 23:08:36 |
| | System | 12 Sep 2020 23:08:36 |

US3402284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-12T19:08:10', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '58f80690-c108-4d9c-98d0-681f5583f1ba' User entered 'No (N)' | System | 12 Sep 2020 23:08:36 |
| | System | 12 Sep 2020 23:08:36 |

US3402284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:25:19

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-12T19:08:15', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '58f80690-c108-4d9c-98d0-681f5583f1ba' User entered 'None (1)' | System | 12 Sep 2020 23:08:36 |
| | System | 12 Sep 2020 23:08:36 |

US3402284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:25:19

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-12T19:08:18', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '58f80690-c108-4d9c-98d0-681f5583f1ba' User entered '12 Sep 2020 19:08' | System | 12 Sep 2020 23:08:36 |
| | System | 12 Sep 2020 23:08:36 |

US3402284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:25:19

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '12 Sep 2020 12:00' | System | 10 Sep 2020 20:20:29 |

US3402284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:25:19

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '13 Sep 2020 11:59' | System | 10 Sep 2020 20:20:29 |

US3402284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| Data entry locked. | System | 10 Sep 2020 20:20:29 |
| User entered 'Day 4' | System | 10 Sep 2020 20:20:29 |

US3402284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:25:19

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-13T20:32:47', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'e5276a25-05c1-42a0-8b1a-71d850675a9b' User entered 'None (1)' | System | 14 Sep 2020 00:33:21 |
| | System | 14 Sep 2020 00:33:21 |

US3402284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:25:19

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-13T20:32:51', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'e5276a25-05c1-42a0-8b1a-71d850675a9b' User entered 'No (N)' | System | 14 Sep 2020 00:33:21 |
| | System | 14 Sep 2020 00:33:21 |

US3402284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-13T20:33:01', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'e5276a25-05c1-42a0-8b1a-71d850675a9b' User entered 'No (N)' | System | 14 Sep 2020 00:33:21 |
| | System | 14 Sep 2020 00:33:21 |

US3402284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:25:19

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-13T20:33:14', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'e5276a25-05c1-42a0-8b1a-71d850675a9b' User entered 'None (1)' | System | 14 Sep 2020 00:33:21 |
| | System | 14 Sep 2020 00:33:21 |

US3402284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:25:19

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-13T20:33:18', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'e5276a25-05c1-42a0-8b1a-71d850675a9b' User entered '13 Sep 2020 20:33' | System | 14 Sep 2020 00:33:21 |
| | System | 14 Sep 2020 00:33:21 |

US3402284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:25:19

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '13 Sep 2020 12:00' | System | 10 Sep 2020 20:20:29 |

US3402284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:25:19

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '14 Sep 2020 11:59' | System | 10 Sep 2020 20:20:29 |

US3402284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| Data entry locked. | System | 10 Sep 2020 20:20:29 |
| User entered 'Day 5' | System | 10 Sep 2020 20:20:29 |

US3402284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:25:19

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-14T19:53:23', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'a411e5ca-9241-4f82-a0bc-02db89f1113b' User entered 'None (1)' | System | 14 Sep 2020 23:53:43 |
| | System | 14 Sep 2020 23:53:43 |

US3402284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:25:19

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-14T19:53:28', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'a411e5ca-9241-4f82-a0bc-02db89f1113b' User entered 'No (N)' | System | 14 Sep 2020 23:53:43 |
| | System | 14 Sep 2020 23:53:43 |

US3402284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-14T19:53:32', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'a411e5ca-9241-4f82-a0bc-02db89f1113b' User entered 'No (N)' | System | 14 Sep 2020 23:53:43 |

US3402284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:25:19

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-14T19:53:37', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'a411e5ca-9241-4f82-a0bc-02db89f1113b' User entered 'None (1)' | System | 14 Sep 2020 23:53:43 |
| | System | 14 Sep 2020 23:53:43 |

US3402284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:25:19

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-14T19:53:41', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'a411e5ca-9241-4f82-a0bc-02db89f1113b' User entered '14 Sep 2020 19:53' | System | 14 Sep 2020 23:53:43 |
| | System | 14 Sep 2020 23:53:43 |

US3402284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:25:19

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '14 Sep 2020 12:00' | System | 10 Sep 2020 20:20:29 |

US3402284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:25:19

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '15 Sep 2020 11:59' | System | 10 Sep 2020 20:20:29 |

US3402284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| Data entry locked. | System | 10 Sep 2020 20:20:29 |
| User entered 'Day 6' | System | 10 Sep 2020 20:20:29 |

US3402284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:25:19

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-15T19:33:33', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'c0b51932-8cc2-4186-ad17-2f13567a580f' User entered 'None (1)' | System | 15 Sep 2020 23:34:11 |
| | System | 15 Sep 2020 23:34:11 |

US3402284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:25:19

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-15T19:33:38', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'c0b51932-8cc2-4186-ad17-2f13567a580f' User entered 'No (N)' | System | 15 Sep 2020 23:34:11 |
| | System | 15 Sep 2020 23:34:11 |

US3402284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-15T19:33:45', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'c0b51932-8cc2-4186-ad17-2f13567a580f' User entered 'No (N)' | System | 15 Sep 2020 23:34:11 |
| | System | 15 Sep 2020 23:34:11 |

US3402284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:25:19

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-15T19:33:53', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'c0b51932-8cc2-4186-ad17-2f13567a580f' User entered 'None (1)' | System | 15 Sep 2020 23:34:11 |
| | System | 15 Sep 2020 23:34:11 |

US3402284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:25:19

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-15T19:33:59', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'c0b51932-8cc2-4186-ad17-2f13567a580f' User entered '15 Sep 2020 19:33' | System | 15 Sep 2020 23:34:11 |
| | System | 15 Sep 2020 23:34:11 |

US3402284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:25:19

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '15 Sep 2020 12:00' | System | 10 Sep 2020 20:20:29 |

US3402284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:25:19

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '16 Sep 2020 11:59' | System | 10 Sep 2020 20:20:29 |

US3402284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| Data entry locked. | System | 10 Sep 2020 20:20:29 |
| User entered 'Day 7' | System | 10 Sep 2020 20:20:29 |

US3402284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:25:19

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-16T20:04:22', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '16c7ae00-196b-4b43-95e8-0f6e0dfc6335' User entered 'None (1)' | System | 17 Sep 2020 00:04:43 |
| | System | 17 Sep 2020 00:04:43 |

US3402284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:25:19

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-16T20:04:27', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '16c7ae00-196b-4b43-95e8-0f6e0dfc6335' User entered 'No (N)' | System | 17 Sep 2020 00:04:43 |
| | System | 17 Sep 2020 00:04:43 |

US3402284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-16T20:04:32', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '16c7ae00-196b-4b43-95e8-0f6e0dfc6335' User entered 'No (N)' | System | 17 Sep 2020 00:04:43 |
| | System | 17 Sep 2020 00:04:43 |

US3402284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:25:19

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-16T20:04:38', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '16c7ae00-196b-4b43-95e8-0f6e0dfc6335' User entered 'None (1)' | System | 17 Sep 2020 00:04:43 |
| | System | 17 Sep 2020 00:04:43 |

US3402284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:25:19

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-16T20:04:41', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '16c7ae00-196b-4b43-95e8-0f6e0dfc6335' User entered '16 Sep 2020 20:04' | System | 17 Sep 2020 00:04:43 |
| | System | 17 Sep 2020 00:04:43 |

US3402284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:25:19

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '16 Sep 2020 12:00' | System | 10 Sep 2020 20:20:29 |

US3402284

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:25:19

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '17 Sep 2020 11:59' | System | 10 Sep 2020 20:20:29 |

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| Data entry locked. | System | 10 Sep 2020 20:20:29 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 10 Sep 2020 20:20:29 |

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:25:19

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-10T16:53:27', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'aca86b29-50b1-4ef0-81a9-e7b32416b688' User entered 'None (0)' | System | 10 Sep 2020 20:54:05 |
| | System | 10 Sep 2020 20:54:05 |

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:25:19

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-10T16:53:32', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'aca86b29-50b1-4ef0-81a9-e7b32416b688' User entered 'None (0)' | System | 10 Sep 2020 20:54:05 |
| | System | 10 Sep 2020 20:54:05 |

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:25:19

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-10T16:53:43', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'aca86b29-50b1-4ef0-81a9-e7b32416b688' User entered 'None (0)' | System | 10 Sep 2020 20:54:05 |
| | System | 10 Sep 2020 20:54:05 |

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:25:19

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-10T16:53:47', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'aca86b29-50b1-4ef0-81a9-e7b32416b688' | System | 10 Sep 2020 20:54:05 |
| User entered 'No interference with activity (1)' | System | 10 Sep 2020 20:54:05 |

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:25:19

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-10T16:53:51', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'aca86b29-50b1-4ef0-81a9-e7b32416b688' User entered 'None (0)' | System | 10 Sep 2020 20:54:05 |
| | System | 10 Sep 2020 20:54:05 |

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:25:19

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-10T16:53:54', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'aca86b29-50b1-4ef0-81a9-e7b32416b688' User entered 'None (0)' | System | 10 Sep 2020 20:54:05 |
| | System | 10 Sep 2020 20:54:05 |

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-10T16:53:58', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'aca86b29-50b1-4ef0-81a9-e7b32416b688' User entered 'No (N)' | System | 10 Sep 2020 20:54:05 |
| | System | 10 Sep 2020 20:54:05 |

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:25:19

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-10T16:54:02', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'aca86b29-50b1-4ef0-81a9-e7b32416b688' User entered '10 Sep 2020 16:54' | System | 10 Sep 2020 20:54:05 |
| | System | 10 Sep 2020 20:54:05 |

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:25:19

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '10 Sep 2020 16:37' | System | 10 Sep 2020 20:20:29 |

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:25:19

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '10 Sep 2020 19:07' | System | 10 Sep 2020 20:20:29 |

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| Data entry locked. | System | 10 Sep 2020 20:20:29 |
| User entered 'Day 1, after vaccination (at home)' | System | 10 Sep 2020 20:20:29 |

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:25:19

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-10T21:30:30', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '8aef555a-c49e-4f99-9691-e121a52eb291' User entered 'None (0)' | System | 11 Sep 2020 01:31:11 |
| | System | 11 Sep 2020 01:31:11 |

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:25:19

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-10T21:30:36', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '8aef555a-c49e-4f99-9691-e121a52eb291' User entered 'None (0)' | System | 11 Sep 2020 01:31:11 |
| | System | 11 Sep 2020 01:31:11 |

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:25:19

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-10T21:30:45', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '8aef555a-c49e-4f99-9691-e121a52eb291' User entered 'None (0)' | System | 11 Sep 2020 01:31:11 |
| | System | 11 Sep 2020 01:31:11 |

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:25:19

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-10T21:30:52', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '8aef555a-c49e-4f99-9691-e121a52eb291' | System | 11 Sep 2020 01:31:11 |
| User entered 'No interference with activity (1)' | System | 11 Sep 2020 01:31:11 |

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:25:19

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-10T21:30:56', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '8aef555a-c49e-4f99-9691-e121a52eb291' User entered 'None (0)' | System | 11 Sep 2020 01:31:11 |
| | System | 11 Sep 2020 01:31:11 |

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:25:19

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-10T21:31:00', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '8aef555a-c49e-4f99-9691-e121a52eb291' User entered 'None (0)' | System | 11 Sep 2020 01:31:11 |
| | System | 11 Sep 2020 01:31:11 |

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-10T21:31:05', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '8aef555a-c49e-4f99-9691-e121a52eb291' | System | 11 Sep 2020 01:31:11 |
| User entered 'No (N)' | System | 11 Sep 2020 01:31:11 |

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:25:19

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-10T21:31:09', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '8aef555a-c49e-4f99-9691-e121a52eb291' User entered '10 Sep 2020 21:31' | System | 11 Sep 2020 01:31:11 |
| | System | 11 Sep 2020 01:31:11 |

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:25:19

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '10 Sep 2020 20:02' | System | 10 Sep 2020 20:20:29 |

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:25:19

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '11 Sep 2020 11:59' | System | 10 Sep 2020 20:20:29 |

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| Data entry locked. | System | 10 Sep 2020 20:20:29 |
| User entered 'Day 2' | System | 10 Sep 2020 20:20:29 |

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:25:19

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-11T19:54:31', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '3d638c87-819d-46d1-8fcf-b5c74241fdb1' User entered 'None (0)' | System | 11 Sep 2020 23:55:08 |
| | System | 11 Sep 2020 23:55:08 |

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:25:19

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-11T19:54:37', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '3d638c87-819d-46d1-8fcf-b5c74241fdb1' | System | 11 Sep 2020 23:55:08 |
| User entered 'No interference with activity (1)' | System | 11 Sep 2020 23:55:08 |

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:25:19

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-11T19:54:42', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '3d638c87-819d-46d1-8fcf-b5c74241fdb1' | System | 11 Sep 2020 23:55:08 |
| User entered 'No interference with activity (1)' | System | 11 Sep 2020 23:55:08 |

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:25:19

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-11T19:54:46', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '3d638c87-819d-46d1-8fcf-b5c74241fdb1' | System | 11 Sep 2020 23:55:08 |
| User entered 'No interference with activity (1)' | System | 11 Sep 2020 23:55:08 |

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:25:19

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-11T19:54:52', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '3d638c87-819d-46d1-8fcf-b5c74241fdb1' User entered 'None (0)' | System | 11 Sep 2020 23:55:08 |
| | System | 11 Sep 2020 23:55:08 |

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:25:19

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-11T19:54:56', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '3d638c87-819d-46d1-8fcf-b5c74241fdb1' User entered 'None (0)' | System | 11 Sep 2020 23:55:08 |
| | System | 11 Sep 2020 23:55:08 |

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-11T19:55:01', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '3d638c87-819d-46d1-8fcf-b5c74241fdb1' User entered 'No (N)' | System | 11 Sep 2020 23:55:08 |
| | System | 11 Sep 2020 23:55:08 |

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:25:19

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-11T19:55:06', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '3d638c87-819d-46d1-8fcf-b5c74241fdb1' User entered '11 Sep 2020 19:55' | System | 11 Sep 2020 23:55:08 |
| | System | 11 Sep 2020 23:55:08 |

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:25:19

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '11 Sep 2020 12:00' | System | 10 Sep 2020 20:20:29 |

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:25:19

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '12 Sep 2020 11:59' | System | 10 Sep 2020 20:20:29 |

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| Data entry locked. | System | 10 Sep 2020 20:20:29 |
| User entered 'Day 3' | System | 10 Sep 2020 20:20:29 |

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:25:19

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-12T19:08:24', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '7f585484-a695-46a3-84e5-80dc527b2adb' User entered 'None (0)' | System | 12 Sep 2020 23:08:56 |
| | System | 12 Sep 2020 23:08:56 |

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:25:19

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-12T19:08:30', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '7f585484-a695-46a3-84e5-80dc527b2adb' | System | 12 Sep 2020 23:08:56 |
| User entered 'No interference with activity (1)' | System | 12 Sep 2020 23:08:56 |

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:25:19

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-12T19:08:35', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '7f585484-a695-46a3-84e5-80dc527b2adb' User entered 'No interference with activity (1)' | System | 12 Sep 2020 23:08:56 |
| | System | 12 Sep 2020 23:08:56 |

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:25:19

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-12T19:08:39', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '7f585484-a695-46a3-84e5-80dc527b2adb' User entered 'No interference with activity (1)' | System | 12 Sep 2020 23:08:56 |
| | System | 12 Sep 2020 23:08:56 |

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:25:19

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-12T19:08:42', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '7f585484-a695-46a3-84e5-80dc527b2adb' User entered 'None (0)' | System | 12 Sep 2020 23:08:56 |
| | System | 12 Sep 2020 23:08:56 |

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:25:19

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-12T19:08:45', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '7f585484-a695-46a3-84e5-80dc527b2adb' User entered 'None (0)' | System | 12 Sep 2020 23:08:56 |
| | System | 12 Sep 2020 23:08:56 |

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-12T19:08:50', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '7f585484-a695-46a3-84e5-80dc527b2adb' User entered 'No (N)' | System | 12 Sep 2020 23:08:56 |
| | System | 12 Sep 2020 23:08:56 |

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:25:19

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-12T19:08:53', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '7f585484-a695-46a3-84e5-80dc527b2adb' User entered '12 Sep 2020 19:08' | System | 12 Sep 2020 23:08:56 |
| | System | 12 Sep 2020 23:08:56 |

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:25:19

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '12 Sep 2020 12:00' | System | 10 Sep 2020 20:20:29 |

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:25:19

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '13 Sep 2020 11:59' | System | 10 Sep 2020 20:20:29 |

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| Data entry locked. | System | 10 Sep 2020 20:20:29 |
| User entered 'Day 4' | System | 10 Sep 2020 20:20:29 |

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:25:19

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-13T20:33:27', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '6f8246df-d215-4d83-bcd5-b87583dbec82' User entered 'None (0)' | System | 14 Sep 2020 00:34:08 |
| | System | 14 Sep 2020 00:34:08 |

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:25:19

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-13T20:33:32', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '6f8246df-d215-4d83-bcd5-b87583dbec82' | System | 14 Sep 2020 00:34:08 |
| User entered 'No interference with activity (1)' | System | 14 Sep 2020 00:34:08 |

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:25:19

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-13T20:33:42', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '6f8246df-d215-4d83-bcd5-b87583dbec82' | System | 14 Sep 2020 00:34:08 |
| User entered 'No interference with activity (1)' | System | 14 Sep 2020 00:34:08 |

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:25:19

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-13T20:33:49', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '6f8246df-d215-4d83-bcd5-b87583dbec82' | System | 14 Sep 2020 00:34:08 |
| User entered 'No interference with activity (1)' | System | 14 Sep 2020 00:34:08 |

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:25:19

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-13T20:33:53', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '6f8246df-d215-4d83-bcd5-b87583dbec82' User entered 'None (0)' | System | 14 Sep 2020 00:34:08 |
| | System | 14 Sep 2020 00:34:08 |

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:25:19

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-13T20:33:56', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '6f8246df-d215-4d83-bcd5-b87583dbec82' User entered 'None (0)' | System | 14 Sep 2020 00:34:08 |
| | System | 14 Sep 2020 00:34:08 |

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-13T20:34:00', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '6f8246df-d215-4d83-bcd5-b87583dbec82' User entered 'No (N)' | System | 14 Sep 2020 00:34:08 |
| | System | 14 Sep 2020 00:34:08 |

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:25:19

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-13T20:34:06', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '6f8246df-d215-4d83-bcd5-b87583dbec82' User entered '13 Sep 2020 20:34' | System | 14 Sep 2020 00:34:08 |
| | System | 14 Sep 2020 00:34:08 |

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:25:19

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '13 Sep 2020 12:00' | System | 10 Sep 2020 20:20:29 |

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:25:19

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '14 Sep 2020 11:59' | System | 10 Sep 2020 20:20:29 |

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| Data entry locked. | System | 10 Sep 2020 20:20:29 |
| User entered 'Day 5' | System | 10 Sep 2020 20:20:29 |

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:25:19

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-14T19:53:50', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '9d19a100-1505-4659-8e7d-085b6b19b543' User entered 'None (0)' | System | 14 Sep 2020 23:54:32 |
| | System | 14 Sep 2020 23:54:32 |

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:25:19

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-14T19:53:56', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '9d19a100-1505-4659-8e7d-085b6b19b543' | System | 14 Sep 2020 23:54:32 |
| User entered 'No interference with activity (1)' | System | 14 Sep 2020 23:54:32 |

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:25:19

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-14T19:54:09', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '9d19a100-1505-4659-8e7d-085b6b19b543' | System | 14 Sep 2020 23:54:32 |
| User entered 'Some interference with activity (2)' | System | 14 Sep 2020 23:54:32 |

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:25:19

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-14T19:54:13', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '9d19a100-1505-4659-8e7d-085b6b19b543' | System | 14 Sep 2020 23:54:32 |
| User entered 'Some interference with activity (2)' | System | 14 Sep 2020 23:54:32 |

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:25:19

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-14T19:54:17', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '9d19a100-1505-4659-8e7d-085b6b19b543' User entered 'None (0)' | System | 14 Sep 2020 23:54:32 |
| | System | 14 Sep 2020 23:54:32 |

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:25:19

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-14T19:54:20', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '9d19a100-1505-4659-8e7d-085b6b19b543' User entered 'None (0)' | System | 14 Sep 2020 23:54:32 |
| | System | 14 Sep 2020 23:54:32 |

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-14T19:54:24', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '9d19a100-1505-4659-8e7d-085b6b19b543' User entered 'No (N)' | System | 14 Sep 2020 23:54:32 |
| | System | 14 Sep 2020 23:54:32 |

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:25:19

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-14T19:54:28', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '9d19a100-1505-4659-8e7d-085b6b19b543' User entered '14 Sep 2020 19:54' | System | 14 Sep 2020 23:54:32 |
| | System | 14 Sep 2020 23:54:32 |

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:25:19

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '14 Sep 2020 12:00' | System | 10 Sep 2020 20:20:29 |

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:25:19

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '15 Sep 2020 11:59' | System | 10 Sep 2020 20:20:29 |

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| Data entry locked. | System | 10 Sep 2020 20:20:29 |
| User entered 'Day 6' | System | 10 Sep 2020 20:20:29 |

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:25:19

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-15T19:34:25', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'd1ac9706-423b-49c8-828c-8dd5c162d62e' | System | 15 Sep 2020 23:35:09 |
| User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)' | System | 15 Sep 2020 23:35:09 |

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:25:19

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-15T19:34:32', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'd1ac9706-423b-49c8-828c-8dd5c162d62e' | System | 15 Sep 2020 23:35:09 |
| User entered 'No interference with activity (1)' | System | 15 Sep 2020 23:35:09 |

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:25:19

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-15T19:34:44', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'd1ac9706-423b-49c8-828c-8dd5c162d62e' | System | 15 Sep 2020 23:35:09 |
| User entered 'No interference with activity (1)' | System | 15 Sep 2020 23:35:09 |

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:25:19

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-15T19:34:50', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'd1ac9706-423b-49c8-828c-8dd5c162d62e' | System | 15 Sep 2020 23:35:09 |
| User entered 'No interference with activity (1)' | System | 15 Sep 2020 23:35:09 |

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:25:19

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-15T19:34:54', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'd1ac9706-423b-49c8-828c-8dd5c162d62e' User entered 'None (0)' | System | 15 Sep 2020 23:35:09 |
| | System | 15 Sep 2020 23:35:09 |

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:25:19

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-15T19:34:57', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'd1ac9706-423b-49c8-828c-8dd5c162d62e' User entered 'None (0)' | System | 15 Sep 2020 23:35:09 |
| | System | 15 Sep 2020 23:35:09 |

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-15T19:35:03', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'd1ac9706-423b-49c8-828c-8dd5c162d62e' User entered 'No (N)' | System | 15 Sep 2020 23:35:09 |
| | System | 15 Sep 2020 23:35:09 |

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:25:19

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-15T19:35:07', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'd1ac9706-423b-49c8-828c-8dd5c162d62e' User entered '15 Sep 2020 19:35' | System | 15 Sep 2020 23:35:09 |
| | System | 15 Sep 2020 23:35:09 |

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:25:19

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '15 Sep 2020 12:00' | System | 10 Sep 2020 20:20:29 |

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:25:19

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '16 Sep 2020 11:59' | System | 10 Sep 2020 20:20:29 |

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| Data entry locked. | System | 10 Sep 2020 20:20:29 |
| User entered 'Day 7' | System | 10 Sep 2020 20:20:29 |

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:25:19

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-16T20:04:49', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '63797e67-76ee-4054-9189-ec8d26e0423b' User entered 'None (0)' | System | 17 Sep 2020 00:05:31 |
| | System | 17 Sep 2020 00:05:31 |

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:25:19

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-16T20:05:00', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '63797e67-76ee-4054-9189-ec8d26e0423b' User entered 'None (0)' | System | 17 Sep 2020 00:05:31 |
| | System | 17 Sep 2020 00:05:31 |

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:25:19

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-16T20:05:04', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '63797e67-76ee-4054-9189-ec8d26e0423b' | System | 17 Sep 2020 00:05:31 |
| User entered 'No interference with activity (1)' | System | 17 Sep 2020 00:05:31 |

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:25:19

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-16T20:05:08', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '63797e67-76ee-4054-9189-ec8d26e0423b' | System | 17 Sep 2020 00:05:31 |
| User entered 'No interference with activity (1)' | System | 17 Sep 2020 00:05:31 |

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:25:19

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-16T20:05:12', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '63797e67-76ee-4054-9189-ec8d26e0423b' User entered 'None (0)' | System | 17 Sep 2020 00:05:31 |
| | System | 17 Sep 2020 00:05:31 |

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:25:19

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-16T20:05:15', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '63797e67-76ee-4054-9189-ec8d26e0423b' User entered 'None (0)' | System | 17 Sep 2020 00:05:31 |
| | System | 17 Sep 2020 00:05:31 |

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-16T20:05:25', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '63797e67-76ee-4054-9189-ec8d26e0423b' User entered 'No (N)' | System | 17 Sep 2020 00:05:31 |
| | System | 17 Sep 2020 00:05:31 |

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:25:19

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-16T20:05:28', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '63797e67-76ee-4054-9189-ec8d26e0423b' User entered '16 Sep 2020 20:05' | System | 17 Sep 2020 00:05:31 |
| | System | 17 Sep 2020 00:05:31 |

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:25:19

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '16 Sep 2020 12:00' | System | 10 Sep 2020 20:20:29 |

US3402284

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:25:19

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '17 Sep 2020 11:59' | System | 10 Sep 2020 20:20:29 |

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| Data entry locked. | System | 15 Sep 2020 23:35:09 |
| User entered 'Day 8' | System | 15 Sep 2020 23:35:09 |

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 17:25:19

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-17T19:44:28', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'b2b1c142-b15b-4897-a755-8b95101653e0' | System | 17 Sep 2020 23:44:37 |
| User entered 'Some interference with activity (2)' | System | 17 Sep 2020 23:44:37 |

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 17:25:19

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-17T19:44:35', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'b2b1c142-b15b-4897-a755-8b95101653e0' User entered '17 Sep 2020 19:44' | System | 17 Sep 2020 23:44:37 |
| | System | 17 Sep 2020 23:44:37 |

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 17:25:19

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '17 Sep 2020 12:00' | System | 15 Sep 2020 23:35:09 |

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 17:25:19

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '18 Sep 2020 11:59' | System | 15 Sep 2020 23:35:09 |

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(9)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| Data entry locked. | System | 17 Sep 2020 00:05:31 |
| User entered 'Day 9' | System | 17 Sep 2020 00:05:31 |

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(9)

Generated On: 09 Jun 2021 17:25:19

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-18T20:53:23', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'b5efe13a-96eb-4570-8b2b-beb1404830a4' | System | 19 Sep 2020 00:53:29 |
| User entered 'Some interference with activity (2)' | System | 19 Sep 2020 00:53:29 |

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(9)

Generated On: 09 Jun 2021 17:25:19

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-18T20:53:27', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'b5efe13a-96eb-4570-8b2b-beb1404830a4' User entered '18 Sep 2020 20:53' | System | 19 Sep 2020 00:53:29 |
| | System | 19 Sep 2020 00:53:29 |

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(9)

Generated On: 09 Jun 2021 17:25:19

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '18 Sep 2020 12:00' | System | 17 Sep 2020 00:05:31 |

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(9)

Generated On: 09 Jun 2021 17:25:19

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '19 Sep 2020 11:59' | System | 17 Sep 2020 00:05:31 |

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(10)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| Data entry locked. | System | 17 Sep 2020 23:44:37 |
| User entered 'Day 10' | System | 17 Sep 2020 23:44:37 |

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(10)

Generated On: 09 Jun 2021 17:25:19

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-19T19:25:33', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '3c2adf27-af40-4f54-9b9f-365a857861aa' | System | 19 Sep 2020 23:25:44 |
| User entered 'No interference with activity (1)' | System | 19 Sep 2020 23:25:44 |

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(10)

Generated On: 09 Jun 2021 17:25:19

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-19T19:25:41', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '3c2adf27-af40-4f54-9b9f-365a857861aa' User entered '19 Sep 2020 19:25' | System | 19 Sep 2020 23:25:44 |
| | System | 19 Sep 2020 23:25:44 |

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(10)

Generated On: 09 Jun 2021 17:25:19

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '19 Sep 2020 12:00' | System | 17 Sep 2020 23:44:37 |

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(10)

Generated On: 09 Jun 2021 17:25:19

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '20 Sep 2020 11:59' | System | 17 Sep 2020 23:44:37 |

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(11)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| Data entry locked. | System | 19 Sep 2020 00:53:29 |
| User entered 'Day 11' | System | 19 Sep 2020 00:53:29 |

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(11)

Generated On: 09 Jun 2021 17:25:19

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-21T05:08:21', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '67da9aaf-210b-41f6-a48c-40adceac95fd' User entered 'No interference with activity (1)' | System | 21 Sep 2020 09:08:27 |
| | System | 21 Sep 2020 09:08:27 |

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(11)

Generated On: 09 Jun 2021 17:25:19

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-21T05:08:25', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '67da9aaf-210b-41f6-a48c-40adceac95fd' User entered '21 Sep 2020 05:08' | System | 21 Sep 2020 09:08:27 |
| | System | 21 Sep 2020 09:08:27 |

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(11)

Generated On: 09 Jun 2021 17:25:19

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '20 Sep 2020 12:00' | System | 19 Sep 2020 00:53:29 |

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(11)

Generated On: 09 Jun 2021 17:25:19

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '21 Sep 2020 11:59' | System | 19 Sep 2020 00:53:29 |

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(12)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| Data entry locked. | System | 19 Sep 2020 23:25:44 |
| User entered 'Day 12' | System | 19 Sep 2020 23:25:44 |

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(12)

Generated On: 09 Jun 2021 17:25:19

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-21T15:28:57', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'a3e2b811-7997-479f-b31b-6c5dec70b683' | System | 21 Sep 2020 19:29:03 |
| User entered 'No interference with activity (1)' | System | 21 Sep 2020 19:29:03 |

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(12)

Generated On: 09 Jun 2021 17:25:19

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-21T15:29:01', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'a3e2b811-7997-479f-b31b-6c5dec70b683' User entered '21 Sep 2020 15:29' | System | 21 Sep 2020 19:29:03 |
| | System | 21 Sep 2020 19:29:03 |

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(12)

Generated On: 09 Jun 2021 17:25:19

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '21 Sep 2020 12:00' | System | 19 Sep 2020 23:25:44 |

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(12)

Generated On: 09 Jun 2021 17:25:19

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '22 Sep 2020 11:59' | System | 19 Sep 2020 23:25:44 |

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(13)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| Data entry locked. | System | 21 Sep 2020 09:08:27 |
| User entered 'Day 13' | System | 21 Sep 2020 09:08:27 |

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(13)

Generated On: 09 Jun 2021 17:25:19

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| | | |

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(13)

Generated On: 09 Jun 2021 17:25:19

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| | | |

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(13)

Generated On: 09 Jun 2021 17:25:19

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '22 Sep 2020 12:00' | System | 21 Sep 2020 09:08:27 |

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(13)

Generated On: 09 Jun 2021 17:25:19

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '23 Sep 2020 11:59' | System | 21 Sep 2020 09:08:27 |

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(14)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| Data entry locked. | System | 21 Sep 2020 19:29:03 |
| User entered 'Day 14' | System | 21 Sep 2020 19:29:03 |

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(14)

Generated On: 09 Jun 2021 17:25:19

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-24T08:18:46', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '3bfde9ff-e687-476d-b56d-3562277b8cc1' | System | 24 Sep 2020 12:18:54 |
| User entered 'No interference with activity (1)' | System | 24 Sep 2020 12:18:54 |

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(14)

Generated On: 09 Jun 2021 17:25:19

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-24T08:18:51', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '3bfde9ff-e687-476d-b56d-3562277b8cc1' User entered '24 Sep 2020 08:18' | System | 24 Sep 2020 12:18:54 |
| | System | 24 Sep 2020 12:18:54 |

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(14)

Generated On: 09 Jun 2021 17:25:19

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '23 Sep 2020 12:00' | System | 21 Sep 2020 19:29:03 |

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(14)

Generated On: 09 Jun 2021 17:25:19

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '24 Sep 2020 11:59' | System | 21 Sep 2020 19:29:03 |

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(15)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| Data entry locked. | System | 24 Sep 2020 12:18:54 |
| User entered 'Day 15' | System | 24 Sep 2020 12:18:54 |

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(15)

Generated On: 09 Jun 2021 17:25:19

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-25T11:40:09', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'f556dbe2-bb47-4aeb-b9e5-94ee59ffa8b7' | System | 25 Sep 2020 15:40:17 |
| User entered 'No interference with activity (1)' | System | 25 Sep 2020 15:40:17 |

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(15)

Generated On: 09 Jun 2021 17:25:19

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-25T11:40:15', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'f556dbe2-bb47-4aeb-b9e5-94ee59ffa8b7' User entered '25 Sep 2020 11:40' | System | 25 Sep 2020 15:40:17 |
| | System | 25 Sep 2020 15:40:17 |

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(15)

Generated On: 09 Jun 2021 17:25:19

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '24 Sep 2020 12:00' | System | 24 Sep 2020 12:18:54 |

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(15)

Generated On: 09 Jun 2021 17:25:19

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '25 Sep 2020 11:59' | System | 24 Sep 2020 12:18:54 |

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(16)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| Data entry locked. | System | 24 Sep 2020 12:18:54 |
| User entered 'Day 16' | System | 24 Sep 2020 12:18:54 |

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(16)

Generated On: 09 Jun 2021 17:25:19

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-26T00:00:47', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '9762326c-645a-4667-889d-77b705fd36b1' | System | 26 Sep 2020 04:00:55 |
| User entered 'No interference with activity (1)' | System | 26 Sep 2020 04:00:55 |

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(16)

Generated On: 09 Jun 2021 17:25:19

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-26T00:00:49', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '9762326c-645a-4667-889d-77b705fd36b1' User entered '26 Sep 2020 00:00' | System | 26 Sep 2020 04:00:55 |
| | System | 26 Sep 2020 04:00:55 |

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(16)

Generated On: 09 Jun 2021 17:25:19

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '25 Sep 2020 12:00' | System | 24 Sep 2020 12:18:54 |

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(16)

Generated On: 09 Jun 2021 17:25:19

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '26 Sep 2020 11:59' | System | 24 Sep 2020 12:18:54 |

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(17)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| Data entry locked. | System | 25 Sep 2020 15:40:17 |
| User entered 'Day 17' | System | 25 Sep 2020 15:40:17 |

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(17)

Generated On: 09 Jun 2021 17:25:19

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-26T17:11:57', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '21853852-1776-4a79-941e-fe2abf6fceb1' | System | 26 Sep 2020 21:12:04 |
| User entered 'No interference with activity (1)' | System | 26 Sep 2020 21:12:04 |

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(17)

Generated On: 09 Jun 2021 17:25:19

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-26T17:12:01', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '21853852-1776-4a79-941e-fe2abf6fceb1' User entered '26 Sep 2020 17:12' | System | 26 Sep 2020 21:12:04 |
| | System | 26 Sep 2020 21:12:04 |

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(17)

Generated On: 09 Jun 2021 17:25:19

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '26 Sep 2020 12:00' | System | 25 Sep 2020 15:40:17 |

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(17)

Generated On: 09 Jun 2021 17:25:19

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '27 Sep 2020 11:59' | System | 25 Sep 2020 15:40:17 |

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(18)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| Data entry locked. | System | 26 Sep 2020 04:00:55 |
| User entered 'Day 18' | System | 26 Sep 2020 04:00:55 |

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(18)

Generated On: 09 Jun 2021 17:25:19

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-27T19:12:26', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '4009a743-c699-447b-99f5-17c2f370ad2c' | System | 27 Sep 2020 23:12:34 |
| User entered 'No interference with activity (1)' | System | 27 Sep 2020 23:12:34 |

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(18)

Generated On: 09 Jun 2021 17:25:19

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-27T19:12:30', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '4009a743-c699-447b-99f5-17c2f370ad2c' User entered '27 Sep 2020 19:12' | System | 27 Sep 2020 23:12:34 |
| | System | 27 Sep 2020 23:12:34 |

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(18)

Generated On: 09 Jun 2021 17:25:19

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '27 Sep 2020 12:00' | System | 26 Sep 2020 04:00:55 |

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(18)

Generated On: 09 Jun 2021 17:25:19

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '28 Sep 2020 11:59' | System | 26 Sep 2020 04:00:55 |

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(19)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| Data entry locked. | System | 26 Sep 2020 21:12:04 |
| User entered 'Day 19' | System | 26 Sep 2020 21:12:04 |

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(19)

Generated On: 09 Jun 2021 17:25:19

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| | | |

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(19)

Generated On: 09 Jun 2021 17:25:19

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| | | |

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(19)

Generated On: 09 Jun 2021 17:25:19

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '28 Sep 2020 12:00' | System | 26 Sep 2020 21:12:04 |

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(19)

Generated On: 09 Jun 2021 17:25:19

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '29 Sep 2020 11:59' | System | 26 Sep 2020 21:12:04 |

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(20)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| Data entry locked. | System | 27 Sep 2020 23:12:34 |
| User entered 'Day 20' | System | 27 Sep 2020 23:12:34 |

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(20)

Generated On: 09 Jun 2021 17:25:19

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-29T15:32:05', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '1c8b7ed9-7c95-4c89-9ec8-7a5d8d6e74c8' | System | 29 Sep 2020 19:32:12 |
| User entered 'No interference with activity (1)' | System | 29 Sep 2020 19:32:12 |

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(20)

Generated On: 09 Jun 2021 17:25:19

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-29T15:32:09', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '1c8b7ed9-7c95-4c89-9ec8-7a5d8d6e74c8' User entered '29 Sep 2020 15:32' | System | 29 Sep 2020 19:32:12 |
| | System | 29 Sep 2020 19:32:12 |

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(20)

Generated On: 09 Jun 2021 17:25:19

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '29 Sep 2020 12:00' | System | 27 Sep 2020 23:12:34 |

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(20)

Generated On: 09 Jun 2021 17:25:19

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '30 Sep 2020 11:59' | System | 27 Sep 2020 23:12:34 |

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(21)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| Data entry locked. | System | 29 Sep 2020 19:32:12 |
| User entered 'Day 21' | System | 29 Sep 2020 19:32:12 |

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(21)

Generated On: 09 Jun 2021 17:25:19

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| | | |

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(21)

Generated On: 09 Jun 2021 17:25:19

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| | | |

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(21)

Generated On: 09 Jun 2021 17:25:19

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '30 Sep 2020 12:00' | System | 29 Sep 2020 19:32:12 |

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(21)

Generated On: 09 Jun 2021 17:25:19

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '01 Oct 2020 11:59' | System | 29 Sep 2020 19:32:12 |

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(22)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| Data entry locked. | System | 29 Sep 2020 19:32:12 |
| User entered 'Day 22' | System | 29 Sep 2020 19:32:12 |

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(22)

Generated On: 09 Jun 2021 17:25:19

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-10-01T20:31:08', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '0e3536db-f150-4885-8b34-09b1a55e9391' | System | 02 Oct 2020 00:31:14 |
| User entered 'No interference with activity (1)' | System | 02 Oct 2020 00:31:14 |

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(22)

Generated On: 09 Jun 2021 17:25:19

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-10-01T20:31:12', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '0e3536db-f150-4885-8b34-09b1a55e9391' User entered '01 Oct 2020 20:31' | System | 02 Oct 2020 00:31:14 |
| | System | 02 Oct 2020 00:31:14 |

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(22)

Generated On: 09 Jun 2021 17:25:19

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '01 Oct 2020 12:00' | System | 29 Sep 2020 19:32:12 |

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(22)

Generated On: 09 Jun 2021 17:25:19

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '02 Oct 2020 11:59' | System | 29 Sep 2020 19:32:12 |

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(23)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| Data entry locked. | System | 02 Oct 2020 00:31:14 |
| User entered 'Day 23' | System | 02 Oct 2020 00:31:14 |

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(23)

Generated On: 09 Jun 2021 17:25:19

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-10-02T20:26:25', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '6be4e1ef-ee1b-4163-8002-39a1efc9e793' | System | 03 Oct 2020 00:26:33 |
| User entered 'No interference with activity (1)' | System | 03 Oct 2020 00:26:33 |

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(23)

Generated On: 09 Jun 2021 17:25:19

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-10-02T20:26:28', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '6be4e1ef-ee1b-4163-8002-39a1efc9e793' User entered '02 Oct 2020 20:26' | System | 03 Oct 2020 00:26:33 |
| | System | 03 Oct 2020 00:26:33 |

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(23)

Generated On: 09 Jun 2021 17:25:19

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '02 Oct 2020 12:00' | System | 02 Oct 2020 00:31:14 |

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(23)

Generated On: 09 Jun 2021 17:25:19

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '03 Oct 2020 11:59' | System | 02 Oct 2020 00:31:14 |

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(24)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| Data entry locked. | System | 02 Oct 2020 00:31:14 |
| User entered 'Day 24' | System | 02 Oct 2020 00:31:14 |

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(24)

Generated On: 09 Jun 2021 17:25:19

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-10-03T20:47:44', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '35a97f77-06c5-4ab5-b4e8-0bef4ddc7ba8' User entered 'None (0)' | System | 04 Oct 2020 00:47:53 |
| | System | 04 Oct 2020 00:47:53 |

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(24)

Generated On: 09 Jun 2021 17:25:19

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-10-03T20:47:48', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '35a97f77-06c5-4ab5-b4e8-0bef4ddc7ba8' User entered '03 Oct 2020 20:47' | System | 04 Oct 2020 00:47:53 |
| | System | 04 Oct 2020 00:47:53 |

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(24)

Generated On: 09 Jun 2021 17:25:19

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '03 Oct 2020 12:00' | System | 02 Oct 2020 00:31:14 |

US3402284

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(24)

Generated On: 09 Jun 2021 17:25:19

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '04 Oct 2020 11:59' | System | 02 Oct 2020 00:31:14 |

US3402284

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(8)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| Data entry locked. | System | 15 Sep 2020 23:35:09 |
| User entered 'Day 8' | System | 15 Sep 2020 23:35:09 |

US3402284

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(8)

Generated On: 09 Jun 2021 17:25:19

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-17T19:44:48', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '4a79b87e-0f91-4b94-a50f-f2a84e6a9f65' | System | 17 Sep 2020 23:44:54 |
| User entered 'No interference with activity (1)' | System | 17 Sep 2020 23:44:54 |

US3402284

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(8)

Generated On: 09 Jun 2021 17:25:19

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-17T19:44:52', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '4a79b87e-0f91-4b94-a50f-f2a84e6a9f65' User entered '17 Sep 2020 19:44' | System | 17 Sep 2020 23:44:54 |
| | System | 17 Sep 2020 23:44:54 |

US3402284

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(8)

Generated On: 09 Jun 2021 17:25:19

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '17 Sep 2020 12:00' | System | 15 Sep 2020 23:35:09 |

US3402284

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(8)

Generated On: 09 Jun 2021 17:25:19

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '18 Sep 2020 11:59' | System | 15 Sep 2020 23:35:09 |

US3402284

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(9)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| Data entry locked. | System | 17 Sep 2020 00:05:31 |
| User entered 'Day 9' | System | 17 Sep 2020 00:05:31 |

US3402284

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(9)

Generated On: 09 Jun 2021 17:25:19

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-18T20:53:36', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'c2341a1c-e3ac-49d8-ab6f-d4de0c677866' | System | 19 Sep 2020 00:53:45 |
| User entered 'Some interference with activity (2)' | System | 19 Sep 2020 00:53:45 |

US3402284

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(9)

Generated On: 09 Jun 2021 17:25:19

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-18T20:53:40', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'c2341a1c-e3ac-49d8-ab6f-d4de0c677866' | System | 19 Sep 2020 00:53:45 |
| User entered '18 Sep 2020 20:53' | System | 19 Sep 2020 00:53:45 |

US3402284

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(9)

Generated On: 09 Jun 2021 17:25:19

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '18 Sep 2020 12:00' | System | 17 Sep 2020 00:05:31 |

US3402284

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(9)

Generated On: 09 Jun 2021 17:25:19

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '19 Sep 2020 11:59' | System | 17 Sep 2020 00:05:31 |

US3402284

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(10)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| Data entry locked. | System | 17 Sep 2020 23:44:54 |
| User entered 'Day 10' | System | 17 Sep 2020 23:44:54 |

US3402284

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(10)

Generated On: 09 Jun 2021 17:25:19

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-19T19:25:19', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '48a562c6-5da0-4941-b124-54b888e143ac' | System | 19 Sep 2020 23:25:30 |
| User entered 'No interference with activity (1)' | System | 19 Sep 2020 23:25:30 |

US3402284

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(10)

Generated On: 09 Jun 2021 17:25:19

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-19T19:25:28', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '48a562c6-5da0-4941-b124-54b888e143ac' User entered '19 Sep 2020 19:25' | System | 19 Sep 2020 23:25:30 |
| | System | 19 Sep 2020 23:25:30 |

US3402284

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(10)

Generated On: 09 Jun 2021 17:25:19

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '19 Sep 2020 12:00' | System | 17 Sep 2020 23:44:54 |

US3402284

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(10)

Generated On: 09 Jun 2021 17:25:19

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '20 Sep 2020 11:59' | System | 17 Sep 2020 23:44:54 |

US3402284

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(11)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| Data entry locked. | System | 19 Sep 2020 00:53:45 |
| User entered 'Day 11' | System | 19 Sep 2020 00:53:45 |

US3402284

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(11)

Generated On: 09 Jun 2021 17:25:19

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-21T05:08:09', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '5d323681-e29d-4918-beb0-8f86d04414d3' | System | 21 Sep 2020 09:08:26 |
| User entered 'No interference with activity (1)' | System | 21 Sep 2020 09:08:26 |

US3402284

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(11)

Generated On: 09 Jun 2021 17:25:19

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-21T05:08:13', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '5d323681-e29d-4918-beb0-8f86d04414d3' User entered '21 Sep 2020 05:08' | System | 21 Sep 2020 09:08:26 |
| | System | 21 Sep 2020 09:08:26 |

US3402284

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(11)

Generated On: 09 Jun 2021 17:25:19

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '20 Sep 2020 12:00' | System | 19 Sep 2020 00:53:45 |

US3402284

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(11)

Generated On: 09 Jun 2021 17:25:19

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '21 Sep 2020 11:59' | System | 19 Sep 2020 00:53:45 |

US3402284

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(12)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| Data entry locked. | System | 19 Sep 2020 23:25:30 |
| User entered 'Day 12' | System | 19 Sep 2020 23:25:30 |

US3402284

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(12)

Generated On: 09 Jun 2021 17:25:19

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-21T15:28:44', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '30c8c0ce-5d5d-4105-8154-3defd2fb5734' | System | 21 Sep 2020 19:28:50 |
| User entered 'No interference with activity (1)' | System | 21 Sep 2020 19:28:50 |

US3402284

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(12)

Generated On: 09 Jun 2021 17:25:19

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-21T15:28:48', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '30c8c0ce-5d5d-4105-8154-3defd2fb5734' User entered '21 Sep 2020 15:28' | System | 21 Sep 2020 19:28:50 |
| | System | 21 Sep 2020 19:28:50 |

US3402284

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(12)

Generated On: 09 Jun 2021 17:25:19

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '21 Sep 2020 12:00' | System | 19 Sep 2020 23:25:30 |

US3402284

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(12)

Generated On: 09 Jun 2021 17:25:19

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '22 Sep 2020 11:59' | System | 19 Sep 2020 23:25:30 |

US3402284

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(13)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| Data entry locked. | System | 21 Sep 2020 09:08:26 |
| User entered 'Day 13' | System | 21 Sep 2020 09:08:26 |

US3402284

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(13)

Generated On: 09 Jun 2021 17:25:19

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| | | |

US3402284

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(13)

Generated On: 09 Jun 2021 17:25:19

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| | | |

US3402284

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(13)

Generated On: 09 Jun 2021 17:25:19

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '22 Sep 2020 12:00' | System | 21 Sep 2020 09:08:26 |

US3402284

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(13)

Generated On: 09 Jun 2021 17:25:19

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '23 Sep 2020 11:59' | System | 21 Sep 2020 09:08:26 |

US3402284

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(14)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| Data entry locked. | System | 21 Sep 2020 19:28:50 |
| User entered 'Day 14' | System | 21 Sep 2020 19:28:50 |

US3402284

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(14)

Generated On: 09 Jun 2021 17:25:19

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-24T08:19:23', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'a7933152-2928-495b-97ee-57a40d974d97' | System | 24 Sep 2020 12:19:31 |
| User entered 'No interference with activity (1)' | System | 24 Sep 2020 12:19:31 |

US3402284

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(14)

Generated On: 09 Jun 2021 17:25:19

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-24T08:19:28', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'a7933152-2928-495b-97ee-57a40d974d97' | System | 24 Sep 2020 12:19:31 |
| User entered '24 Sep 2020 08:19' | System | 24 Sep 2020 12:19:31 |

US3402284

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(14)

Generated On: 09 Jun 2021 17:25:19

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '23 Sep 2020 12:00' | System | 21 Sep 2020 19:28:50 |

US3402284

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(14)

Generated On: 09 Jun 2021 17:25:19

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '24 Sep 2020 11:59' | System | 21 Sep 2020 19:28:50 |

US3402284

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(15)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| Data entry locked. | System | 24 Sep 2020 12:19:31 |
| User entered 'Day 15' | System | 24 Sep 2020 12:19:31 |

US3402284

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(15)

Generated On: 09 Jun 2021 17:25:19

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-25T11:39:58', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '4d7b890a-bbba-4624-bed6-77a53466e388' | System | 25 Sep 2020 15:40:05 |
| User entered 'No interference with activity (1)' | System | 25 Sep 2020 15:40:05 |

US3402284

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(15)

Generated On: 09 Jun 2021 17:25:19

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-25T11:40:02', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '4d7b890a-bbba-4624-bed6-77a53466e388' User entered '25 Sep 2020 11:40' | System | 25 Sep 2020 15:40:05 |
| | System | 25 Sep 2020 15:40:05 |

US3402284

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(15)

Generated On: 09 Jun 2021 17:25:19

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '24 Sep 2020 12:00' | System | 24 Sep 2020 12:19:31 |

US3402284

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(15)

Generated On: 09 Jun 2021 17:25:19

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '25 Sep 2020 11:59' | System | 24 Sep 2020 12:19:31 |

US3402284

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(16)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| Data entry locked. | System | 24 Sep 2020 12:19:31 |
| User entered 'Day 16' | System | 24 Sep 2020 12:19:31 |

US3402284

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(16)

Generated On: 09 Jun 2021 17:25:19

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-26T00:00:33', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '46326e79-43a4-4b6b-af0d-423ca71537f8' | System | 26 Sep 2020 04:00:45 |
| User entered 'No interference with activity (1)' | System | 26 Sep 2020 04:00:45 |

US3402284

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(16)

Generated On: 09 Jun 2021 17:25:19

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-26T00:00:36', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '46326e79-43a4-4b6b-af0d-423ca71537f8' User entered '26 Sep 2020 00:00' | System | 26 Sep 2020 04:00:45 |
| | System | 26 Sep 2020 04:00:45 |

US3402284

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(16)

Generated On: 09 Jun 2021 17:25:19

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '25 Sep 2020 12:00' | System | 24 Sep 2020 12:19:31 |

US3402284

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(16)

Generated On: 09 Jun 2021 17:25:19

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '26 Sep 2020 11:59' | System | 24 Sep 2020 12:19:31 |

US3402284

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(17)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| Data entry locked. | System | 25 Sep 2020 15:40:05 |
| User entered 'Day 17' | System | 25 Sep 2020 15:40:05 |

US3402284

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(17)

Generated On: 09 Jun 2021 17:25:19

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-26T17:11:43', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '634a2701-6134-43bb-82b2-809e11f0139d' | System | 26 Sep 2020 21:11:49 |
| User entered 'No interference with activity (1)' | System | 26 Sep 2020 21:11:49 |

US3402284

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(17)

Generated On: 09 Jun 2021 17:25:19

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-26T17:11:47', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '634a2701-6134-43bb-82b2-809e11f0139d' User entered '26 Sep 2020 17:11' | System | 26 Sep 2020 21:11:49 |
| | System | 26 Sep 2020 21:11:49 |

US3402284

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(17)

Generated On: 09 Jun 2021 17:25:19

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '26 Sep 2020 12:00' | System | 25 Sep 2020 15:40:05 |

US3402284

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(17)

Generated On: 09 Jun 2021 17:25:19

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '27 Sep 2020 11:59' | System | 25 Sep 2020 15:40:05 |

US3402284

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(18)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| Data entry locked. | System | 26 Sep 2020 04:00:45 |
| User entered 'Day 18' | System | 26 Sep 2020 04:00:45 |

US3402284

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(18)

Generated On: 09 Jun 2021 17:25:19

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-27T19:12:14', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '2a6282ab-874f-4bc7-a95a-c80dd38d2c1b' User entered 'No interference with activity (1)' | System | 27 Sep 2020 23:12:19 |
| | System | 27 Sep 2020 23:12:19 |

US3402284

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(18)

Generated On: 09 Jun 2021 17:25:19

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-27T19:12:18', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '2a6282ab-874f-4bc7-a95a-c80dd38d2c1b' User entered '27 Sep 2020 19:12' | System | 27 Sep 2020 23:12:19 |
| | System | 27 Sep 2020 23:12:19 |

US3402284

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(18)

Generated On: 09 Jun 2021 17:25:19

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '27 Sep 2020 12:00' | System | 26 Sep 2020 04:00:45 |

US3402284

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(18)

Generated On: 09 Jun 2021 17:25:19

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '28 Sep 2020 11:59' | System | 26 Sep 2020 04:00:45 |

US3402284

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(19)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| Data entry locked. | System | 26 Sep 2020 21:11:49 |
| User entered 'Day 19' | System | 26 Sep 2020 21:11:49 |

US3402284

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(19)

Generated On: 09 Jun 2021 17:25:19

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| | | |

US3402284

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(19)

Generated On: 09 Jun 2021 17:25:19

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| | | |

US3402284

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(19)

Generated On: 09 Jun 2021 17:25:19

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '28 Sep 2020 12:00' | System | 26 Sep 2020 21:11:49 |

US3402284

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(19)

Generated On: 09 Jun 2021 17:25:19

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '29 Sep 2020 11:59' | System | 26 Sep 2020 21:11:49 |

US3402284

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(20)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| Data entry locked. | System | 27 Sep 2020 23:12:19 |
| User entered 'Day 20' | System | 27 Sep 2020 23:12:19 |

US3402284

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(20)

Generated On: 09 Jun 2021 17:25:19

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-29T15:31:56', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '1bb09e55-a8b3-41cf-9937-ce4c5152dce1' User entered 'None (0)' | System | 29 Sep 2020 19:32:04 |
| | System | 29 Sep 2020 19:32:04 |

US3402284

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(20)

Generated On: 09 Jun 2021 17:25:19

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-29T15:32:00', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '1bb09e55-a8b3-41cf-9937-ce4c5152dce1' User entered '29 Sep 2020 15:32' | System | 29 Sep 2020 19:32:04 |
| | System | 29 Sep 2020 19:32:04 |

US3402284

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(20)

Generated On: 09 Jun 2021 17:25:19

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '29 Sep 2020 12:00' | System | 27 Sep 2020 23:12:19 |

US3402284

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(20)

Generated On: 09 Jun 2021 17:25:19

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '30 Sep 2020 11:59' | System | 27 Sep 2020 23:12:19 |

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| Data entry locked. | System | 15 Sep 2020 23:33:26 |
| User entered 'Day 8' | System | 15 Sep 2020 23:33:26 |

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-17T19:45:00', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '9e932b6d-fe6a-4207-a45c-3e00653f26b6' User entered 'No (N)' | System | 17 Sep 2020 23:45:05 |
| | System | 17 Sep 2020 23:45:05 |

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:25:19

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-17T19:45:03', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '9e932b6d-fe6a-4207-a45c-3e00653f26b6' User entered '17 Sep 2020 19:45' | System | 17 Sep 2020 23:45:05 |
| | System | 17 Sep 2020 23:45:05 |

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:25:19

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '17 Sep 2020 12:00' | System | 15 Sep 2020 23:33:26 |

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:25:19

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '18 Sep 2020 11:59' | System | 15 Sep 2020 23:33:26 |

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| Data entry locked. | System | 17 Sep 2020 00:05:31 |
| User entered 'Day 9' | System | 17 Sep 2020 00:05:31 |

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-18T20:53:00', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'c6c71e2c-8ef8-47ee-9971-970c48577471' User entered 'No (N)' | System | 19 Sep 2020 00:53:07 |
| | System | 19 Sep 2020 00:53:07 |

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 17:25:19

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-18T20:53:04', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'c6c71e2c-8ef8-47ee-9971-970c48577471' User entered '18 Sep 2020 20:53' | System | 19 Sep 2020 00:53:07 |
| | System | 19 Sep 2020 00:53:07 |

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 17:25:19

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '18 Sep 2020 12:00' | System | 17 Sep 2020 00:05:31 |

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 17:25:19

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '19 Sep 2020 11:59' | System | 17 Sep 2020 00:05:31 |

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| Data entry locked. | System | 17 Sep 2020 23:44:37 |
| User entered 'Day 10' | System | 17 Sep 2020 23:44:37 |

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-19T19:25:08', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '8f617029-2be4-47a4-a12b-db18c1e97da4' User entered 'No (N)' | System | 19 Sep 2020 23:25:13 |
| | System | 19 Sep 2020 23:25:13 |

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 17:25:19

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-19T19:25:12', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '8f617029-2be4-47a4-a12b-db18c1e97da4' | System | 19 Sep 2020 23:25:13 |
| User entered '19 Sep 2020 19:25' | System | 19 Sep 2020 23:25:13 |

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 17:25:19

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '19 Sep 2020 12:00' | System | 17 Sep 2020 23:44:37 |

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 17:25:19

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '20 Sep 2020 11:59' | System | 17 Sep 2020 23:44:37 |

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| Data entry locked. | System | 19 Sep 2020 00:53:29 |
| User entered 'Day 11' | System | 19 Sep 2020 00:53:29 |

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-21T05:07:43', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '46306563-5bcd-463c-a4ec-4db4cf4631e8' User entered 'No (N)' | System | 21 Sep 2020 09:08:00 |
| | System | 21 Sep 2020 09:08:00 |

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 17:25:19

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-21T05:07:58', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '46306563-5bcd-463c-a4ec-4db4cf4631e8' User entered '21 Sep 2020 05:07' | System | 21 Sep 2020 09:08:00 |
| | System | 21 Sep 2020 09:08:00 |

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 17:25:19

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '20 Sep 2020 12:00' | System | 19 Sep 2020 00:53:29 |

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 17:25:19

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '21 Sep 2020 11:59' | System | 19 Sep 2020 00:53:29 |

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(12)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| Data entry locked. | System | 19 Sep 2020 23:25:30 |
| User entered 'Day 12' | System | 19 Sep 2020 23:25:30 |

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(12)

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-21T15:28:27', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '24ea314f-b3c6-44aa-a6ae-4c996ab9363f' User entered 'No (N)' | System | 21 Sep 2020 19:28:41 |
| | System | 21 Sep 2020 19:28:41 |

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(12)

Generated On: 09 Jun 2021 17:25:19

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-21T15:28:37', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '24ea314f-b3c6-44aa-a6ae-4c996ab9363f' User entered '21 Sep 2020 15:28' | System | 21 Sep 2020 19:28:41 |
| | System | 21 Sep 2020 19:28:41 |

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(12)

Generated On: 09 Jun 2021 17:25:19

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '21 Sep 2020 12:00' | System | 19 Sep 2020 23:25:30 |

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(12)

Generated On: 09 Jun 2021 17:25:19

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '22 Sep 2020 11:59' | System | 19 Sep 2020 23:25:30 |

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(13)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| Data entry locked. | System | 21 Sep 2020 09:08:26 |
| User entered 'Day 13' | System | 21 Sep 2020 09:08:26 |

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(13)

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| | | |

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(13)

Generated On: 09 Jun 2021 17:25:19

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| | | |

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(13)

Generated On: 09 Jun 2021 17:25:19

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '22 Sep 2020 12:00' | System | 21 Sep 2020 09:08:26 |

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(13)

Generated On: 09 Jun 2021 17:25:19

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '23 Sep 2020 11:59' | System | 21 Sep 2020 09:08:26 |

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(14)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| Data entry locked. | System | 21 Sep 2020 19:28:50 |
| User entered 'Day 14' | System | 21 Sep 2020 19:28:50 |

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(14)

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-24T08:19:06', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '288f36ae-2536-4b00-8abc-51e866cc31e9' User entered 'Yes (Y)' | System | 24 Sep 2020 12:19:12 |
| | System | 24 Sep 2020 12:19:12 |

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(14)

Generated On: 09 Jun 2021 17:25:19

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-24T08:19:11', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '288f36ae-2536-4b00-8abc-51e866cc31e9' User entered '24 Sep 2020 08:19' | System | 24 Sep 2020 12:19:12 |
| | System | 24 Sep 2020 12:19:12 |

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(14)

Generated On: 09 Jun 2021 17:25:19

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '23 Sep 2020 12:00' | System | 21 Sep 2020 19:28:50 |

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(14)

Generated On: 09 Jun 2021 17:25:19

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '24 Sep 2020 11:59' | System | 21 Sep 2020 19:28:50 |

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(15)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| Data entry locked. | System | 24 Sep 2020 12:18:54 |
| User entered 'Day 15' | System | 24 Sep 2020 12:18:54 |

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(15)

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-25T11:39:46', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'b7a20f36-06c9-43d9-b34a-365635ad1583' User entered 'No (N)' | System | 25 Sep 2020 15:39:55 |
| | System | 25 Sep 2020 15:39:55 |

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(15)

Generated On: 09 Jun 2021 17:25:19

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-25T11:39:50', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'b7a20f36-06c9-43d9-b34a-365635ad1583' User entered '25 Sep 2020 11:39' | System | 25 Sep 2020 15:39:55 |
| | System | 25 Sep 2020 15:39:55 |

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(15)

Generated On: 09 Jun 2021 17:25:19

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '24 Sep 2020 12:00' | System | 24 Sep 2020 12:18:54 |

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(15)

Generated On: 09 Jun 2021 17:25:19

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '25 Sep 2020 11:59' | System | 24 Sep 2020 12:18:54 |

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(16)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| Data entry locked. | System | 24 Sep 2020 12:18:54 |
| User entered 'Day 16' | System | 24 Sep 2020 12:18:54 |

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(16)

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-26T00:00:25', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'd34b448d-113e-4832-90cc-4ecc4f14d83d' User entered 'No (N)' | System | 26 Sep 2020 04:00:32 |
| | System | 26 Sep 2020 04:00:32 |

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(16)

Generated On: 09 Jun 2021 17:25:19

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-26T00:00:27', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'd34b448d-113e-4832-90cc-4ecc4f14d83d' User entered '26 Sep 2020 00:00' | System | 26 Sep 2020 04:00:32 |
| | System | 26 Sep 2020 04:00:32 |

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(16)

Generated On: 09 Jun 2021 17:25:19

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '25 Sep 2020 12:00' | System | 24 Sep 2020 12:18:54 |

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(16)

Generated On: 09 Jun 2021 17:25:19

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '26 Sep 2020 11:59' | System | 24 Sep 2020 12:18:54 |

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(17)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| Data entry locked. | System | 25 Sep 2020 15:40:05 |
| User entered 'Day 17' | System | 25 Sep 2020 15:40:05 |

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(17)

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-26T17:11:29', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'f65c066d-2eed-405a-b930-95c4b7f6d199' User entered 'No (N)' | System | 26 Sep 2020 21:11:36 |
| | System | 26 Sep 2020 21:11:36 |

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(17)

Generated On: 09 Jun 2021 17:25:19

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-26T17:11:33', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'f65c066d-2eed-405a-b930-95c4b7f6d199' | System | 26 Sep 2020 21:11:36 |
| User entered '26 Sep 2020 17:11' | System | 26 Sep 2020 21:11:36 |

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(17)

Generated On: 09 Jun 2021 17:25:19

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '26 Sep 2020 12:00' | System | 25 Sep 2020 15:40:05 |

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(17)

Generated On: 09 Jun 2021 17:25:19

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '27 Sep 2020 11:59' | System | 25 Sep 2020 15:40:05 |

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(18)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| Data entry locked. | System | 26 Sep 2020 04:00:45 |
| User entered 'Day 18' | System | 26 Sep 2020 04:00:45 |

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(18)

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-27T19:11:59', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '01910572-c373-45e5-a512-842e04d20cd9' User entered 'No (N)' | System | 27 Sep 2020 23:12:05 |
| | System | 27 Sep 2020 23:12:05 |

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(18)

Generated On: 09 Jun 2021 17:25:19

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-27T19:12:03', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '01910572-c373-45e5-a512-842e04d20cd9' User entered '27 Sep 2020 19:12' | System | 27 Sep 2020 23:12:05 |
| | System | 27 Sep 2020 23:12:05 |

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(18)

Generated On: 09 Jun 2021 17:25:19

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '27 Sep 2020 12:00' | System | 26 Sep 2020 04:00:45 |

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(18)

Generated On: 09 Jun 2021 17:25:19

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '28 Sep 2020 11:59' | System | 26 Sep 2020 04:00:45 |

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(19)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| Data entry locked. | System | 26 Sep 2020 21:11:49 |
| User entered 'Day 19' | System | 26 Sep 2020 21:11:49 |

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(19)

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| | | |

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(19)

Generated On: 09 Jun 2021 17:25:19

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| | | |

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(19)

Generated On: 09 Jun 2021 17:25:19

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '28 Sep 2020 12:00' | System | 26 Sep 2020 21:11:49 |

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(19)

Generated On: 09 Jun 2021 17:25:19

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '29 Sep 2020 11:59' | System | 26 Sep 2020 21:11:49 |

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(20)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| Data entry locked. | System | 27 Sep 2020 23:12:19 |
| User entered 'Day 20' | System | 27 Sep 2020 23:12:19 |

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(20)

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-29T15:31:45', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'b0f604c3-6efe-4a27-a8d0-ab4328de11e7' | System | 29 Sep 2020 19:32:00 |
| User entered 'No (N)' | System | 29 Sep 2020 19:32:00 |

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(20)

Generated On: 09 Jun 2021 17:25:19

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-09-29T15:31:50', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'b0f604c3-6efe-4a27-a8d0-ab4328de11e7' User entered '29 Sep 2020 15:31' | System | 29 Sep 2020 19:32:00 |
| | System | 29 Sep 2020 19:32:00 |

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(20)

Generated On: 09 Jun 2021 17:25:19

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '29 Sep 2020 12:00' | System | 27 Sep 2020 23:12:19 |

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(20)

Generated On: 09 Jun 2021 17:25:19

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '30 Sep 2020 11:59' | System | 27 Sep 2020 23:12:19 |

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(21)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| Data entry locked. | System | 29 Sep 2020 19:32:12 |
| User entered 'Day 21' | System | 29 Sep 2020 19:32:12 |

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(21)

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| | | |

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(21)

Generated On: 09 Jun 2021 17:25:19

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| | | |

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(21)

Generated On: 09 Jun 2021 17:25:19

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '30 Sep 2020 12:00' | System | 29 Sep 2020 19:32:12 |

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(21)

Generated On: 09 Jun 2021 17:25:19

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '01 Oct 2020 11:59' | System | 29 Sep 2020 19:32:12 |

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(22)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| Data entry locked. | System | 29 Sep 2020 19:32:12 |
| User entered 'Day 22' | System | 29 Sep 2020 19:32:12 |

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(22)

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-10-01T20:30:58', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'a2f09d68-dd92-4de1-bc2c-3e731af791a2' | System | 02 Oct 2020 00:31:05 |
| User entered 'No (N)' | System | 02 Oct 2020 00:31:05 |

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(22)

Generated On: 09 Jun 2021 17:25:19

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-10-01T20:31:02', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'a2f09d68-dd92-4de1-bc2c-3e731af791a2' User entered '01 Oct 2020 20:31' | System | 02 Oct 2020 00:31:05 |
| | System | 02 Oct 2020 00:31:05 |

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(22)

Generated On: 09 Jun 2021 17:25:19

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '01 Oct 2020 12:00' | System | 29 Sep 2020 19:32:12 |

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(22)

Generated On: 09 Jun 2021 17:25:19

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '02 Oct 2020 11:59' | System | 29 Sep 2020 19:32:12 |

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(23)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| Data entry locked. | System | 02 Oct 2020 00:31:14 |
| User entered 'Day 23' | System | 02 Oct 2020 00:31:14 |

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(23)

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-10-02T20:26:14', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '55d9fad9-673e-4f38-aad7-66dbd2f81a18' User entered 'No (N)' | System | 03 Oct 2020 00:26:19 |
| | System | 03 Oct 2020 00:26:19 |

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(23)

Generated On: 09 Jun 2021 17:25:19

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-10-02T20:26:17', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '55d9fad9-673e-4f38-aad7-66dbd2f81a18' User entered '02 Oct 2020 20:26' | System | 03 Oct 2020 00:26:19 |
| | System | 03 Oct 2020 00:26:19 |

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(23)

Generated On: 09 Jun 2021 17:25:19

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '02 Oct 2020 12:00' | System | 02 Oct 2020 00:31:14 |

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(23)

Generated On: 09 Jun 2021 17:25:19

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '03 Oct 2020 11:59' | System | 02 Oct 2020 00:31:14 |

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(24)

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| Data entry locked. | System | 02 Oct 2020 00:31:14 |
| User entered 'Day 24' | System | 02 Oct 2020 00:31:14 |

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(24)

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-10-03T20:47:35', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'b41504e4-ef29-4eaf-9e64-6f1a8a52937a' User entered 'No (N)' | System | 04 Oct 2020 00:47:41 |
| | System | 04 Oct 2020 00:47:41 |

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(24)

Generated On: 09 Jun 2021 17:25:19

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-10-03T20:47:38', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'b41504e4-ef29-4eaf-9e64-6f1a8a52937a' User entered '03 Oct 2020 20:47' | System | 04 Oct 2020 00:47:41 |
| | System | 04 Oct 2020 00:47:41 |

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(24)

Generated On: 09 Jun 2021 17:25:19

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '03 Oct 2020 12:00' | System | 02 Oct 2020 00:31:14 |

US3402284

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(24)

Generated On: 09 Jun 2021 17:25:19

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User entered '04 Oct 2020 11:59' | System | 02 Oct 2020 00:31:14 |

US3402284

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:25:19

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered 'Yes (Y)' | (b) (4) Traci Hull (b) (4) | 17 Sep 2020 18:55:58 |

US3402284

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:25:19

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered '17 Sep 2020' | Traci Hull (b) (4) | 17 Sep 2020 18:55:58 |

US3402284

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:25:19

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered 'Contact Made (CONTACT MADE)' | Traci Hull (b) (4) | 17 Sep 2020 18:55:58 |

US3402284

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:25:19

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered empty. | Traci Hull (b) (4) | 17 Sep 2020 18:55:58 |

US3402284

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:25:19

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered 'Yes (Y)' | Traci Hull (b) (4) | 17 Sep 2020 18:56:02 |

US3402284

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:25:19

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User entered 'I' | System | 17 Sep 2020 18:56:02 |

US3402284

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:25:19

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered 'Yes (Y)' | (b) (4) Traci Hull (b) (4) (b) (4) | 08 Oct 2020 15:17:43 |

US3402284

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:25:19

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered '24 Sep 2020' | Traci Hull (b) (4) | 08 Oct 2020 15:17:43 |

US3402284

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:25:19

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered 'Contact Made (CONTACT MADE)' | Traci Hull (b) (4) | 08 Oct 2020 15:17:43 |

US3402284

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:25:19

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered empty. | Traci Hull (b) (4) | 08 Oct 2020 15:17:43 |

US3402284

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:25:19

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered 'Yes (Y)' | Traci Hull (b) (4) | 05 Oct 2020 20:12:04 |

US3402284

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:25:19

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User entered 'I' | System | 05 Oct 2020 20:12:04 |

US3402284

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:25:19

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered 'Yes (Y)' | (b) (4) Traci Hull (b) (4) | 05 Oct 2020 20:12:25 |

US3402284

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:25:19

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|---|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered '02 Oct 2020' reason for change: New Information | Traci Hull (b) (4) | 11 Nov 2020 12:47:45 |
| User entered '2 Oct 2020' | Traci Hull (b) (4) | 05 Oct 2020 20:12:25 |

US3402284

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:25:19

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered 'Contact Made (CONTACT MADE)' | Traci Hull (b) (4) | 05 Oct 2020 20:12:25 |

US3402284

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:25:19

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered empty. | Traci Hull (b) (4) | 05 Oct 2020 20:12:25 |

US3402284

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:25:19

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User closed query 'Data is required. Please complete.' (Site from System). | (b) (4) | |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 05 Oct 2020 20:12:35 |
| User entered 'Yes (Y)' reason for change: Per Query Resolution | Traci Hull (b) (4) | 05 Oct 2020 20:12:35 |
| User opened query 'Data is required. Please complete.' (Site from System). | (b) (4) | |
| User entered empty. | System | 05 Oct 2020 20:12:29 |
| | Traci Hull (b) (4) | 05 Oct 2020 20:12:29 |
| | (b) (4) | |

US3402284

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:25:19

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User entered '1' | System | 05 Oct 2020 20:12:35 |
| User entered empty. | System | 05 Oct 2020 20:12:29 |

US3402284

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:25:19

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:44 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered 'Yes (Y)' | (b) (4) Traci Hull (b) (4) | 08 Oct 2020 20:39:46 |

US3402284

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|---|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:44 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered '08 Oct 2020' reason for change: New Information | Traci Hull (b) (4) | 11 Nov 2020 12:48:50 |
| User entered '8 Oct 2020' | Traci Hull (b) (4) | 08 Oct 2020 20:39:46 |

US3402284

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|--------------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:44 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered 'Clinic (Clinic)' | Traci Hull (b) (4) | 08 Oct 2020 20:39:46 |

US3402284

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:25:19

[Folder OID](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:44 |
| User entered 'VISIT3' | System | 08 Oct 2020 20:39:46 |

US3402284

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:25:19

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:44 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered 'Yes (Y)' | Traci Hull (b) (4) | 08 Oct 2020 20:41:43 |

US3402284

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:25:19

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:44 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered '08 Oct 2020' reason for change: New Information | Traci Hull (b) (4) | 11 Nov 2020 12:49:02 |
| User entered '8 Oct 2020' | Traci Hull (b) (4) | 08 Oct 2020 20:41:43 |

US3402284

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:44 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered '15:04' | (b) (4) Traci Hull (b) (4) (b) (4) | 08 Oct 2020 20:41:43 |

US3402284

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:44 |
| User entered '08 Oct 2020 15:04' | System | 11 Nov 2020 12:49:02 |
| User entered '8 Oct 2020 15:04' | System | 08 Oct 2020 20:41:43 |

US3402284

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:44 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered '98.7' F | Traci Hull (b) (4) | 08 Oct 2020 20:41:43 |

US3402284

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:25:19

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:44 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered 'Oral (Oral)' | (b) (4) Traci Hull (b) (4) (b) (4) | 08 Oct 2020 20:41:43 |

US3402284

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:25:19

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:44 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered empty. | (b) (4) | |
| | Traci Hull (b) (4) | 08 Oct 2020 20:41:43 |
| | (b) (4) | |

US3402284

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:25:19

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:44 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered '88' | Traci Hull (b) (4) | 08 Oct 2020 20:41:43 |

US3402284

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:25:19

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:44 |
| User entered 'bpm' | System | 08 Oct 2020 20:41:43 |

US3402284

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:44 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered '14' | (b) (4) Traci Hull (b) (4) | 08 Oct 2020 20:41:43 |

US3402284

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:25:19

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:44 |
| User entered 'breaths/min' | System | 08 Oct 2020 20:41:43 |

US3402284

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:44 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered '122' | (b) (4) Traci Hull (b) (4) | 08 Oct 2020 20:41:43 |

US3402284

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:25:19

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:44 |
| User entered 'mmHg' | System | 08 Oct 2020 20:41:43 |

US3402284

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:25:19

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:44 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered '80' | (b) (4) Traci Hull (b) (4) (b) (4) | 08 Oct 2020 20:41:43 |

US3402284

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:25:19

Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:44 |
| User entered 'mmHg' | System | 08 Oct 2020 20:41:43 |

US3402284

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:25:19

[Height \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:44 |
| | | |

US3402284

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:25:19

[Weight \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:44 |
| | | |

US3402284

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:25:19

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered 'No (N)' | (b) (4) Traci Hull (b) (4) | 08 Oct 2020 20:41:51 |

US3402284

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:25:19

Date of examination (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered empty. | Traci Hull (b) (4) | 08 Oct 2020 20:41:51 |

US3402284

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:25:19

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered 'Yes (Y)' | (b) (4) Traci Hull (b) (4) | 08 Oct 2020 20:42:02 |

US3402284

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:25:19

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered '08 Oct 2020' reason for change: New Information | Traci Hull (b) (4) | 11 Nov 2020 12:49:18 |
| User entered '8 Oct 2020' | Traci Hull (b) (4) | 08 Oct 2020 20:42:02 |

US3402284

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:25:19

[Collection time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered '15:17' | (b) (4) | |
| | Traci Hull (b) (4) | 08 Oct 2020 20:42:02 |
| | (b) (4) | |

US3402284

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User entered '08 Oct 2020 15:17' | System | 11 Nov 2020 12:49:18 |
| User entered '8 Oct 2020 15:17' | System | 08 Oct 2020 20:42:02 |

US3402284

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:25:19

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User signature succeeded. | Frank Eder (b) (4) | 15 Feb 2021 17:46:51 |
| User entered 'Yes (Y)' | Traci Hull (b) (4) | 08 Oct 2020 20:42:06 |

US3402284

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:25:19

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User entered 'I' | System | 08 Oct 2020 20:42:06 |

US3402284

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| Data entry locked. | System | 08 Aug 2020 13:01:15 |
| User entered 'Day 64' | System | 08 Aug 2020 13:01:15 |

US3402284

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|---|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| User closed query 'Per DM CLR: 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) | 03 Nov 2020 13:52:20 |
| Query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' answered with 'Patient was contacted patient was feeling sick due to kidney stones. AE has already been added. no further action is needed' (Site from DM). | Tammy Kohn (b) (4) (b) (4) | 02 Nov 2020 14:43:36 |
| User opened query 'Per DM CLR: 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) | 31 Oct 2020 07:03:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-10-08T14:27:36', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '57e4cab2-5eea-4628-828f-3d8f907f6ccb' | System | 08 Oct 2020 18:28:45 |
| User entered 'Yes (Y)' | System | 08 Oct 2020 18:28:45 |

US3402284

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-10-08T14:27:44', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '57e4cab2-5eea-4628-828f-3d8f907f6ccb' User entered 'Yes (Y)' | System | 08 Oct 2020 18:28:45 |
| | System | 08 Oct 2020 18:28:45 |

US3402284

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Please 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) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-10-08T14:28:01', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '57e4cab2-5eea-4628-828f-3d8f907f6ccb' | System | 08 Oct 2020 18:28:45 |
| User entered 'I confirm I have read this message and will call the study clinic immediately (9)' | System | 08 Oct 2020 18:28:45 |

US3402284

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

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) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-10-08T14:28:09', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '57e4cab2-5eea-4628-828f-3d8f907f6ccb' User entered 'No (N)' | System | 08 Oct 2020 18:28:45 |
| | System | 08 Oct 2020 18:28:45 |

US3402284

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

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) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-10-08T14:28:17', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '57e4cab2-5eea-4628-828f-3d8f907f6ccb' User entered 'Yes (Y)' | System | 08 Oct 2020 18:28:45 |
| | System | 08 Oct 2020 18:28:45 |

US3402284

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Please 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) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-10-08T14:28:28', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '57e4cab2-5eea-4628-828f-3d8f907f6ccb' | System | 08 Oct 2020 18:28:45 |
| User entered 'I confirm I have read this message and will call the study clinic immediately (9)' | System | 08 Oct 2020 18:28:45 |

US3402284

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-10-08T14:28:34', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '57e4cab2-5eea-4628-828f-3d8f907f6ccb' User entered '08 Oct 2020 14:28:34' | System | 08 Oct 2020 18:28:45 |
| | System | 08 Oct 2020 18:28:45 |

US3402284

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| Data entry locked. | System | 08 Aug 2020 13:01:15 |
| User entered '08 Oct 2020 00:01' | System | 08 Aug 2020 13:01:15 |

US3402284

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| Data entry locked. | System | 08 Aug 2020 13:01:15 |
| User entered '12 Oct 2020 23:59' | System | 08 Aug 2020 13:01:15 |

US3402284

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| Data entry locked. | System | 08 Aug 2020 13:01:15 |
| User entered 'Day 71' | System | 08 Aug 2020 13:01:15 |

US3402284

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-10-15T10:29:09', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'd90afd8e-1bd6-4380-bb20-b63e8faad12e' User entered 'No (N)' | System | 15 Oct 2020 14:30:23 |
| | System | 15 Oct 2020 14:30:23 |

US3402284

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-10-15T10:29:19', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'd90afd8e-1bd6-4380-bb20-b63e8faad12e' | System | 15 Oct 2020 14:30:23 |
| User entered 'Yes (Y)' | System | 15 Oct 2020 14:30:23 |

US3402284

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Please 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) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-10-15T10:29:33', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'd90afd8e-1bd6-4380-bb20-b63e8faad12e' | System | 15 Oct 2020 14:30:23 |
| User entered 'I confirm I have read this message and will call the study clinic immediately (9)' | System | 15 Oct 2020 14:30:23 |

US3402284

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-10-15T10:29:38', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'd90afd8e-1bd6-4380-bb20-b63e8faad12e' User entered '15 Oct 2020 10:29:38' | System | 15 Oct 2020 14:30:23 |
| | System | 15 Oct 2020 14:30:23 |

US3402284

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| Data entry locked. | System | 08 Aug 2020 13:01:15 |
| User entered '15 Oct 2020 00:01' | System | 08 Aug 2020 13:01:15 |

US3402284

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| Data entry locked. | System | 08 Aug 2020 13:01:15 |
| User entered '19 Oct 2020 23:59' | System | 08 Aug 2020 13:01:15 |

US3402284

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| Data entry locked. | System | 08 Aug 2020 13:01:15 |
| User entered 'Day 78' | System | 08 Aug 2020 13:01:15 |

US3402284

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-10-22T20:20:52', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '5ac93e84-ba57-4546-b6c5-5244ed557959' User entered 'No (N)' | System | 23 Oct 2020 00:21:57 |
| | System | 23 Oct 2020 00:21:57 |

US3402284

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-10-22T20:21:44', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '5ac93e84-ba57-4546-b6c5-5244ed557959' | System | 23 Oct 2020 00:21:57 |
| User entered 'No (N)' | System | 23 Oct 2020 00:21:57 |

US3402284

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-10-22T20:21:55', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '5ac93e84-ba57-4546-b6c5-5244ed557959' User entered '22 Oct 2020 20:21:55' | System | 23 Oct 2020 00:21:57 |
| | System | 23 Oct 2020 00:21:57 |

US3402284

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| Data entry locked. | System | 08 Aug 2020 13:01:15 |
| User entered '22 Oct 2020 00:01' | System | 08 Aug 2020 13:01:15 |

US3402284

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| Data entry locked. | System | 08 Aug 2020 13:01:15 |
| User entered '26 Oct 2020 23:59' | System | 08 Aug 2020 13:01:15 |

US3402284

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| Data entry locked. | System | 08 Aug 2020 13:01:15 |
| User entered 'Day 92' | System | 08 Aug 2020 13:01:15 |

US3402284

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-11-05T15:45:11', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '1e08403c-74cd-4c43-a554-553b61476a73' | System | 05 Nov 2020 20:45:42 |
| User entered 'No (N)' | System | 05 Nov 2020 20:45:42 |

US3402284

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-11-05T15:45:22', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '1e08403c-74cd-4c43-a554-553b61476a73' | System | 05 Nov 2020 20:45:42 |
| User entered 'No (N)' | System | 05 Nov 2020 20:45:42 |

US3402284

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-11-05T15:45:33', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '1e08403c-74cd-4c43-a554-553b61476a73' User entered '05 Nov 2020 15:45:33' | System | 05 Nov 2020 20:45:42 |
| | System | 05 Nov 2020 20:45:42 |

US3402284

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| Data entry locked. | System | 08 Aug 2020 13:01:15 |
| User entered '05 Nov 2020 00:01' | System | 08 Aug 2020 13:01:15 |

US3402284

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| Data entry locked. | System | 08 Aug 2020 13:01:15 |
| User entered '09 Nov 2020 23:59' | System | 08 Aug 2020 13:01:15 |

US3402284

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| Data entry locked. | System | 08 Aug 2020 13:01:15 |
| User entered 'Day 99' | System | 08 Aug 2020 13:01:15 |

US3402284

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-11-12T10:33:12', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'bfde2e34-09a9-4c04-b41b-33af73d5e1e3' | System | 12 Nov 2020 15:33:33 |
| User entered 'No (N)' | System | 12 Nov 2020 15:33:33 |

US3402284

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-11-12T10:33:24', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'bfde2e34-09a9-4c04-b41b-33af73d5e1e3' | System | 12 Nov 2020 15:33:33 |
| User entered 'No (N)' | System | 12 Nov 2020 15:33:33 |

US3402284

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-11-12T10:33:30', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'bfde2e34-09a9-4c04-b41b-33af73d5e1e3' User entered '12 Nov 2020 10:33:30' | System | 12 Nov 2020 15:33:33 |
| | System | 12 Nov 2020 15:33:33 |

US3402284

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| Data entry locked. | System | 08 Aug 2020 13:01:15 |
| User entered '12 Nov 2020 00:01' | System | 08 Aug 2020 13:01:15 |

US3402284

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 04:17:37 |
| Data entry locked. | System | 08 Aug 2020 13:01:15 |
| User entered '16 Nov 2020 23:59' | System | 08 Aug 2020 13:01:15 |

US3402284

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 06:39:57 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 16:26:47 |
| Data entry locked. | System | 08 Aug 2020 13:01:15 |
| User entered 'Day 106' | System | 08 Aug 2020 13:01:15 |

US3402284

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 06:39:57 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 06:39:57 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Please 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) | 26 Apr 2021 06:39:57 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 06:39:57 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

Fever (Temperature \geq 100.4°F/38°C)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 06:39:57 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Chills](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 06:39:57 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Cough](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 06:39:57 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Shortness of breath](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 06:39:57 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Difficulty breathing](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 06:39:57 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Fatigue](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 06:39:57 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Muscle aches](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 06:39:57 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Body aches](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 06:39:57 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Headache](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 06:39:57 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[New loss of taste](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 06:39:57 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[New loss of smell](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 06:39:57 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Sore throat](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 06:39:57 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Congestion](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 06:39:57 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Runny nose](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 06:39:57 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Nausea](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 06:39:57 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Vomiting](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 06:39:57 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Diarrhea](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 06:39:57 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

Please 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) | 26 Apr 2021 06:39:57 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 06:39:57 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Please 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) | 26 Apr 2021 06:39:57 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 06:39:57 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 06:39:57 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 16:26:47 |
| Data entry locked. | System | 08 Aug 2020 13:01:15 |
| User entered '19 Nov 2020 00:01' | System | 08 Aug 2020 13:01:15 |

US3402284

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 06:39:57 |
| DataPoint activated (WR#5335027) | System | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System | 19 Nov 2020 16:26:47 |
| Data entry locked. | System | 08 Aug 2020 13:01:15 |
| User entered '23 Nov 2020 23:59' | System | 08 Aug 2020 13:01:15 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered 'Day 103' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[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 (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-11-19T16:48:01', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '0446a28a-962e-48e6-b68f-f3c873349a5b' User entered 'No (N)' | System | 19 Nov 2020 21:48:34 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

Have you been exposed to someone with 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 (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-11-19T16:48:12', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '0446a28a-962e-48e6-b68f-f3c873349a5b' User entered 'No (N)' | System | 19 Nov 2020 21:48:34 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-11-19T16:48:31', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '0446a28a-962e-48e6-b68f-f3c873349a5b' User entered '19 Nov 2020 16:48:31' | System | 19 Nov 2020 21:48:34 |
| | System | 19 Nov 2020 21:48:34 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '16 Nov 2020 00:01' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '20 Nov 2020 23:59' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered 'Day 110' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[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 (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-11-26T11:14:28', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '4e99def8-874a-4d20-9f61-14a36c9dfd90' | System | 26 Nov 2020 16:14:43 |
| User entered 'No (N)' | System | 26 Nov 2020 16:14:43 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

Have you been exposed to someone with 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 (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-11-26T11:14:35', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '4e99def8-874a-4d20-9f61-14a36c9dfd90' | System | 26 Nov 2020 16:14:43 |
| User entered 'No (N)' | System | 26 Nov 2020 16:14:43 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-11-26T11:14:40', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '4e99def8-874a-4d20-9f61-14a36c9dfd90' User entered '26 Nov 2020 11:14:40' | System | 26 Nov 2020 16:14:43 |
| | System | 26 Nov 2020 16:14:43 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '23 Nov 2020 00:01' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '27 Nov 2020 23:59' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered 'Day 117' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[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 (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-12-02T21:35:30', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '99a3abcd-24c4-4e8c-969a-1f807c3f14ed' User entered 'No (N)' | System | 03 Dec 2020 02:35:51 |
| | System | 03 Dec 2020 02:35:51 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

Have you been exposed to someone with 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 (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-12-02T21:35:44', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '99a3abcd-24c4-4e8c-969a-1f807c3f14ed' User entered 'No (N)' | System | 03 Dec 2020 02:35:51 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-12-02T21:35:47', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '99a3abcd-24c4-4e8c-969a-1f807c3f14ed' User entered '02 Dec 2020 21:35:47' | System | 03 Dec 2020 02:35:51 |
| | System | 03 Dec 2020 02:35:51 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '30 Nov 2020 00:01' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '04 Dec 2020 23:59' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered 'Day 124' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[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 (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-12-09T19:03:44', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '1d4efce4-0280-4caa-8254-0f9ab5894c3a' User entered 'No (N)' | System | 10 Dec 2020 00:04:02 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

Have you been exposed to someone with 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 (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-12-09T19:03:52', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '1d4efce4-0280-4caa-8254-0f9ab5894c3a' User entered 'No (N)' | System | 10 Dec 2020 00:04:02 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-12-09T19:03:56', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '1d4efce4-0280-4caa-8254-0f9ab5894c3a' User entered '09 Dec 2020 19:03:56' | System | 10 Dec 2020 00:04:02 |
| | System | 10 Dec 2020 00:04:02 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '07 Dec 2020 00:01' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '11 Dec 2020 23:59' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered 'Day 131' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[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 (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-12-16T18:22:40', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '46ca746a-394e-494c-b446-c776ccff9278' | System | 16 Dec 2020 23:22:52 |
| User entered 'No (N)' | System | 16 Dec 2020 23:22:52 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Have you been exposed to someone with 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 (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-12-16T18:22:46', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '46ca746a-394e-494c-b446-c776ccff9278' User entered 'No (N)' | System | 16 Dec 2020 23:22:52 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-12-16T18:22:50', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '46ca746a-394e-494c-b446-c776ccff9278' User entered '16 Dec 2020 18:22:50' | System | 16 Dec 2020 23:22:52 |
| | System | 16 Dec 2020 23:22:52 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '14 Dec 2020 00:01' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '18 Dec 2020 23:59' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered 'Day 138' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[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 (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-12-24T22:08:55', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '662492b4-841b-4c5e-b1e4-7ff28c68c620' | System | 25 Dec 2020 03:09:08 |
| User entered 'No (N)' | System | 25 Dec 2020 03:09:08 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

Have you been exposed to someone with 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 (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-12-24T22:09:00', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '662492b4-841b-4c5e-b1e4-7ff28c68c620' | System | 25 Dec 2020 03:09:08 |
| User entered 'No (N)' | System | 25 Dec 2020 03:09:08 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-12-24T22:09:05', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '662492b4-841b-4c5e-b1e4-7ff28c68c620' | System | 25 Dec 2020 03:09:08 |
| User entered '24 Dec 2020 22:09:05' | System | 25 Dec 2020 03:09:08 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '21 Dec 2020 00:01' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '25 Dec 2020 23:59' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered 'Day 145' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[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 (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-12-31T12:38:14', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '90099eaf-4406-4ca4-8231-29071b9b7c14' User entered 'No (N)' | System | 31 Dec 2020 17:38:30 |
| | System | 31 Dec 2020 17:38:30 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

Have you been exposed to someone with 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 (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-12-31T12:38:23', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '90099eaf-4406-4ca4-8231-29071b9b7c14' User entered 'No (N)' | System | 31 Dec 2020 17:38:30 |
| | System | 31 Dec 2020 17:38:30 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2020-12-31T12:38:27', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '90099eaf-4406-4ca4-8231-29071b9b7c14' User entered '31 Dec 2020 12:38:27' | System | 31 Dec 2020 17:38:30 |
| | System | 31 Dec 2020 17:38:30 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '28 Dec 2020 00:01' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '01 Jan 2021 23:59' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered 'Day 152' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[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 (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2021-01-04T20:13:14', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'c5a96cdf-8eec-4612-8544-44375a430d23' | System | 05 Jan 2021 01:13:49 |
| User entered 'No (N)' | System | 05 Jan 2021 01:13:49 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

Have you been exposed to someone with 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 (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2021-01-04T20:13:42', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'c5a96cdf-8eec-4612-8544-44375a430d23' | System | 05 Jan 2021 01:13:49 |
| User entered 'No (N)' | System | 05 Jan 2021 01:13:49 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2021-01-04T20:13:47', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'c5a96cdf-8eec-4612-8544-44375a430d23' User entered '04 Jan 2021 20:13:47' | System | 05 Jan 2021 01:13:49 |
| | System | 05 Jan 2021 01:13:49 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '04 Jan 2021 00:01' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '08 Jan 2021 23:59' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered 'Day 159' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[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 (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2021-01-11T08:47:24', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '99e3140e-f88d-443a-b7a8-de8587bc9940' User entered 'Yes (Y)' | System | 11 Jan 2021 13:50:33 |
| | System | 11 Jan 2021 13:50:33 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

Have you been exposed to someone with 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 (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2021-01-11T08:47:36', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '99e3140e-f88d-443a-b7a8-de8587bc9940' User entered 'Yes (Y)' | System | 11 Jan 2021 13:50:33 |
| | System | 11 Jan 2021 13:50:33 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

Please 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 (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2021-01-11T08:47:56', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '99e3140e-f88d-443a-b7a8-de8587bc9940' | System | 11 Jan 2021 13:50:33 |
| User entered 'I confirm I have read this message and will call the study clinic immediately (9)' | System | 11 Jan 2021 13:50:33 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[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 (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2021-01-11T08:48:25', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '99e3140e-f88d-443a-b7a8-de8587bc9940' User entered 'Yes (Y)' | System | 11 Jan 2021 13:50:33 |
| | System | 11 Jan 2021 13:50:33 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

Fever (Temperature \geq 100.4°F/38°C)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2021-01-11T08:49:03', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '99e3140e-f88d-443a-b7a8-de8587bc9940' User entered '0' | System | 11 Jan 2021 13:50:33 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Chills](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2021-01-11T08:49:03', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '99e3140e-f88d-443a-b7a8-de8587bc9940' User entered '0' | System | 11 Jan 2021 13:50:33 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Cough](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2021-01-11T08:49:03', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '99e3140e-f88d-443a-b7a8-de8587bc9940' User entered '0' | System | 11 Jan 2021 13:50:33 |
| | System | 11 Jan 2021 13:50:33 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Shortness of breath](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2021-01-11T08:49:03', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '99e3140e-f88d-443a-b7a8-de8587bc9940' User entered '0' | System | 11 Jan 2021 13:50:33 |
| | System | 11 Jan 2021 13:50:33 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Difficulty breathing](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2021-01-11T08:49:03', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '99e3140e-f88d-443a-b7a8-de8587bc9940' User entered '0' | System | 11 Jan 2021 13:50:33 |
| | System | 11 Jan 2021 13:50:33 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Fatigue](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2021-01-11T08:49:03', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '99e3140e-f88d-443a-b7a8-de8587bc9940' User entered '0' | System | 11 Jan 2021 13:50:33 |
| | System | 11 Jan 2021 13:50:33 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Muscle aches](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2021-01-11T08:49:03', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '99e3140e-f88d-443a-b7a8-de8587bc9940' User entered '1' | System | 11 Jan 2021 13:50:33 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Body aches](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2021-01-11T08:49:03', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '99e3140e-f88d-443a-b7a8-de8587bc9940' User entered '1' | System | 11 Jan 2021 13:50:33 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Headache](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2021-01-11T08:49:03', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '99e3140e-f88d-443a-b7a8-de8587bc9940' User entered '0' | System | 11 Jan 2021 13:50:33 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[New loss of taste](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2021-01-11T08:49:03', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '99e3140e-f88d-443a-b7a8-de8587bc9940' User entered '0' | System | 11 Jan 2021 13:50:33 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[New loss of smell](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2021-01-11T08:49:03', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '99e3140e-f88d-443a-b7a8-de8587bc9940' User entered '0' | System | 11 Jan 2021 13:50:33 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Sore throat](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2021-01-11T08:49:03', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '99e3140e-f88d-443a-b7a8-de8587bc9940' User entered '0' | System | 11 Jan 2021 13:50:33 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Congestion](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2021-01-11T08:49:03', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '99e3140e-f88d-443a-b7a8-de8587bc9940' User entered '0' | System | 11 Jan 2021 13:50:33 |
| | System | 11 Jan 2021 13:50:33 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Runny nose](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2021-01-11T08:49:03', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '99e3140e-f88d-443a-b7a8-de8587bc9940' User entered '1' | System | 11 Jan 2021 13:50:33 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Nausea](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2021-01-11T08:49:03', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '99e3140e-f88d-443a-b7a8-de8587bc9940' User entered '0' | System | 11 Jan 2021 13:50:33 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Vomiting](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2021-01-11T08:49:03', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '99e3140e-f88d-443a-b7a8-de8587bc9940' User entered '0' | System | 11 Jan 2021 13:50:33 |
| | System | 11 Jan 2021 13:50:33 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Diarrhea](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2021-01-11T08:49:03', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '99e3140e-f88d-443a-b7a8-de8587bc9940' User entered '0' | System | 11 Jan 2021 13:50:33 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Please 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 (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2021-01-11T08:49:10', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '99e3140e-f88d-443a-b7a8-de8587bc9940' | System | 11 Jan 2021 13:50:33 |
| User entered 'I confirm I have read this message and will call the study clinic immediately (9)' | System | 11 Jan 2021 13:50:33 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[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 (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2021-01-11T08:50:05', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '99e3140e-f88d-443a-b7a8-de8587bc9940' User entered 'Yes (Y)' | System | 11 Jan 2021 13:50:33 |
| | System | 11 Jan 2021 13:50:33 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Please 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 (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2021-01-11T08:50:14', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '99e3140e-f88d-443a-b7a8-de8587bc9940' | System | 11 Jan 2021 13:50:33 |
| User entered 'I confirm I have read this message and will call the study clinic immediately (9)' | System | 11 Jan 2021 13:50:33 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2021-01-11T08:50:23', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '99e3140e-f88d-443a-b7a8-de8587bc9940' User entered '11 Jan 2021 08:50:23' | System | 11 Jan 2021 13:50:33 |
| | System | 11 Jan 2021 13:50:33 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '11 Jan 2021 00:01' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '15 Jan 2021 23:59' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered 'Day 166' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[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 (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2021-01-19T09:35:58', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '2ae7c5e0-6cd2-4a34-9eaf-950a266972d8' User entered 'Yes (Y)' | System | 19 Jan 2021 14:39:01 |
| | System | 19 Jan 2021 14:39:01 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

Have you been exposed to someone with 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 (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2021-01-19T09:38:24', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '2ae7c5e0-6cd2-4a34-9eaf-950a266972d8' | System | 19 Jan 2021 14:39:01 |
| User entered 'Yes (Y)' | System | 19 Jan 2021 14:39:01 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Please 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 (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2021-01-19T09:38:45', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '2ae7c5e0-6cd2-4a34-9eaf-950a266972d8' | System | 19 Jan 2021 14:39:01 |
| User entered 'I confirm I have read this message and will call the study clinic immediately (9)' | System | 19 Jan 2021 14:39:01 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[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 (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2021-01-19T09:36:31', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '2ae7c5e0-6cd2-4a34-9eaf-950a266972d8' User entered 'No (N)' | System | 19 Jan 2021 14:39:01 |
| | System | 19 Jan 2021 14:39:01 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[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 (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2021-01-19T09:37:23', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '2ae7c5e0-6cd2-4a34-9eaf-950a266972d8' User entered 'Yes (Y)' | System | 19 Jan 2021 14:39:01 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Please 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 (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2021-01-19T09:36:59', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '2ae7c5e0-6cd2-4a34-9eaf-950a266972d8' | System | 19 Jan 2021 14:39:01 |
| User entered 'I confirm I have read this message and will call the study clinic immediately (9)' | System | 19 Jan 2021 14:39:01 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2021-01-19T09:38:50', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '2ae7c5e0-6cd2-4a34-9eaf-950a266972d8' User entered '19 Jan 2021 09:38:50' | System | 19 Jan 2021 14:39:01 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '18 Jan 2021 00:01' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '22 Jan 2021 23:59' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered 'Day 173' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[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 (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2021-01-29T06:36:26', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '2e026d48-d404-4318-9080-1acd1697647b' User entered 'No (N)' | System | 29 Jan 2021 11:37:01 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

Have you been exposed to someone with 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 (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2021-01-29T06:36:45', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '2e026d48-d404-4318-9080-1acd1697647b' User entered 'No (N)' | System | 29 Jan 2021 11:37:01 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2021-01-29T06:36:49', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '2e026d48-d404-4318-9080-1acd1697647b' User entered '29 Jan 2021 06:36:49' | System | 29 Jan 2021 11:37:01 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '25 Jan 2021 00:01' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '29 Jan 2021 23:59' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered 'Day 180' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[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 (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2021-02-02T17:19:05', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'f700cfba-8bff-4c4a-8117-3730c83516a6' | System | 02 Feb 2021 22:19:22 |
| User entered 'No (N)' | System | 02 Feb 2021 22:19:22 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

Have you been exposed to someone with 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 (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2021-02-02T17:19:14', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'f700cfba-8bff-4c4a-8117-3730c83516a6' | System | 02 Feb 2021 22:19:22 |
| User entered 'No (N)' | System | 02 Feb 2021 22:19:22 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2021-02-02T17:19:18', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'f700cfba-8bff-4c4a-8117-3730c83516a6' | System | 02 Feb 2021 22:19:22 |
| User entered '02 Feb 2021 17:19:18' | System | 02 Feb 2021 22:19:22 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '01 Feb 2021 00:01' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '05 Feb 2021 23:59' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered 'Day 187' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[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 (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2021-02-08T18:37:35', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '22151ad7-b74b-4f53-a1cf-175ca3d26000' User entered 'No (N)' | System | 08 Feb 2021 23:37:48 |
| | System | 08 Feb 2021 23:37:48 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

Have you been exposed to someone with 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 (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2021-02-08T18:37:39', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '22151ad7-b74b-4f53-a1cf-175ca3d26000' | System | 08 Feb 2021 23:37:48 |
| User entered 'No (N)' | System | 08 Feb 2021 23:37:48 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2021-02-08T18:37:46', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '22151ad7-b74b-4f53-a1cf-175ca3d26000' User entered '08 Feb 2021 18:37:46' | System | 08 Feb 2021 23:37:48 |
| | System | 08 Feb 2021 23:37:48 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '08 Feb 2021 00:01' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '12 Feb 2021 23:59' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered 'Day 194' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '15 Feb 2021 00:01' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '19 Feb 2021 23:59' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered 'Day 201' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[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 (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2021-02-22T15:57:27-05:00', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '13b32192-303a-452e-963c-f33fd809167f' User entered 'No (N)' | System | 22 Feb 2021 20:57:42 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

Have you been exposed to someone with 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 (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2021-02-22T15:57:32-05:00', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '13b32192-303a-452e-963c-f33fd809167f' User entered 'No (N)' | System | 22 Feb 2021 20:57:42 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2021-02-22T15:57:38-05:00', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '13b32192-303a-452e-963c-f33fd809167f' | System | 22 Feb 2021 20:57:42 |
| User entered '22 Feb 2021 20:57:38' | System | 22 Feb 2021 20:57:42 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '22 Feb 2021 00:01' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '26 Feb 2021 23:59' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered 'Day 208' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[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 (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2021-03-03T15:51:05-05:00', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '1f6ad7f8-5bd1-4eb7-b7b4-bec1bd9cc29d' | System | 03 Mar 2021 20:51:18 |
| User entered 'No (N)' | System | 03 Mar 2021 20:51:18 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

Have you been exposed to someone with 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 (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2021-03-03T15:51:10-05:00', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '1f6ad7f8-5bd1-4eb7-b7b4-bec1bd9cc29d' | System | 03 Mar 2021 20:51:18 |
| User entered 'No (N)' | System | 03 Mar 2021 20:51:18 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2021-03-03T15:51:13-05:00', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '1f6ad7f8-5bd1-4eb7-b7b4-bec1bd9cc29d' User entered '03 Mar 2021 15:51:13' | System | 03 Mar 2021 20:51:18 |
| | System | 03 Mar 2021 20:51:18 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '01 Mar 2021 00:01' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '05 Mar 2021 23:59' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered 'Day 215' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[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 (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2021-03-08T18:23:30-05:00', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'd361275a-7454-4f32-87df-1c64c0704819' | System | 08 Mar 2021 23:25:23 |
| User entered 'No (N)' | System | 08 Mar 2021 23:25:23 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

Have you been exposed to someone with 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 (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2021-03-08T18:23:35-05:00', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'd361275a-7454-4f32-87df-1c64c0704819' | System | 08 Mar 2021 23:25:23 |
| User entered 'No (N)' | System | 08 Mar 2021 23:25:23 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2021-03-08T18:23:39-05:00', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'd361275a-7454-4f32-87df-1c64c0704819' User entered '08 Mar 2021 18:23:39' | System | 08 Mar 2021 23:25:23 |
| | System | 08 Mar 2021 23:25:23 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '08 Mar 2021 00:01' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '12 Mar 2021 23:59' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered 'Day 222' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[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 (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2021-03-19T05:18:21-04:00', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '119879fd-c06e-4bc8-8d26-6c537c024e2a' | System | 19 Mar 2021 09:18:37 |
| User entered 'No (N)' | System | 19 Mar 2021 09:18:37 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

Have you been exposed to someone with 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 (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2021-03-19T05:18:29-04:00', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '119879fd-c06e-4bc8-8d26-6c537c024e2a' | System | 19 Mar 2021 09:18:37 |
| User entered 'No (N)' | System | 19 Mar 2021 09:18:37 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2021-03-19T05:18:33-04:00', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '119879fd-c06e-4bc8-8d26-6c537c024e2a' User entered '19 Mar 2021 05:18:33' | System | 19 Mar 2021 09:18:37 |
| | System | 19 Mar 2021 09:18:37 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '15 Mar 2021 00:01' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '19 Mar 2021 23:59' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered 'Day 229' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[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 (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2021-03-23T19:55:45-04:00', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'f30865b0-1951-4aab-9d68-b64866730892' | System | 23 Mar 2021 23:56:09 |
| User entered 'No (N)' | System | 23 Mar 2021 23:56:09 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

Have you been exposed to someone with 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 (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2021-03-23T19:55:54-04:00', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'f30865b0-1951-4aab-9d68-b64866730892' | System | 23 Mar 2021 23:56:09 |
| User entered 'No (N)' | System | 23 Mar 2021 23:56:09 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2021-03-23T19:56:01-04:00', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'f30865b0-1951-4aab-9d68-b64866730892' | System | 23 Mar 2021 23:56:09 |
| User entered '23 Mar 2021 19:56:01' | System | 23 Mar 2021 23:56:09 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '22 Mar 2021 00:01' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '26 Mar 2021 23:59' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered 'Day 236' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[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 (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2021-03-31T16:17:00-04:00', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '391bc3a8-0a2f-46fe-859b-809a7de872fc' | System | 31 Mar 2021 20:17:14 |
| User entered 'No (N)' | System | 31 Mar 2021 20:17:14 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

Have you been exposed to someone with 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 (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2021-03-31T16:17:07-04:00', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '391bc3a8-0a2f-46fe-859b-809a7de872fc' | System | 31 Mar 2021 20:17:14 |
| User entered 'No (N)' | System | 31 Mar 2021 20:17:14 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2021-03-31T16:17:10-04:00', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '391bc3a8-0a2f-46fe-859b-809a7de872fc' User entered '31 Mar 2021 16:17:10' | System | 31 Mar 2021 20:17:14 |
| | System | 31 Mar 2021 20:17:14 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '29 Mar 2021 00:01' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '02 Apr 2021 23:59' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered 'Day 243' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[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 (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2021-04-08T20:01:31-04:00', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'd42e4bbe-8c67-4251-8197-64ce9fb1aae9' | System | 09 Apr 2021 00:01:43 |
| User entered 'No (N)' | System | 09 Apr 2021 00:01:43 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

Have you been exposed to someone with 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 (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2021-04-08T20:01:37-04:00', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'd42e4bbe-8c67-4251-8197-64ce9fb1aae9' | System | 09 Apr 2021 00:01:43 |
| User entered 'No (N)' | System | 09 Apr 2021 00:01:43 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2021-04-08T20:01:41-04:00', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'd42e4bbe-8c67-4251-8197-64ce9fb1aae9' | System | 09 Apr 2021 00:01:43 |
| User entered '08 Apr 2021 20:01:41' | System | 09 Apr 2021 00:01:43 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '05 Apr 2021 00:01' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '09 Apr 2021 23:59' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered 'Day 250' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[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 (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2021-04-13T21:06:41-04:00', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'fb02808d-9bd0-4343-92ab-8e4d7541188f' | System | 14 Apr 2021 01:11:13 |
| User entered 'No (N)' | System | 14 Apr 2021 01:11:13 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

Have you been exposed to someone with 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 (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2021-04-13T21:06:52-04:00', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'fb02808d-9bd0-4343-92ab-8e4d7541188f' | System | 14 Apr 2021 01:11:13 |
| User entered 'No (N)' | System | 14 Apr 2021 01:11:13 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2021-04-13T21:06:55-04:00', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'fb02808d-9bd0-4343-92ab-8e4d7541188f' | System | 14 Apr 2021 01:11:13 |
| User entered '13 Apr 2021 21:06:55' | System | 14 Apr 2021 01:11:13 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '12 Apr 2021 00:01' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '16 Apr 2021 23:59' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered 'Day 257' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[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 (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2021-04-21T17:57:27-04:00', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '2c056ebc-3319-4c61-9b79-5f7461780e07' | System | 21 Apr 2021 21:57:48 |
| User entered 'No (N)' | System | 21 Apr 2021 21:57:48 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

Have you been exposed to someone with 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 (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2021-04-21T17:57:37-04:00', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '2c056ebc-3319-4c61-9b79-5f7461780e07' User entered 'No (N)' | System | 21 Apr 2021 21:57:48 |
| | System | 21 Apr 2021 21:57:48 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2021-04-21T17:57:46-04:00', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '2c056ebc-3319-4c61-9b79-5f7461780e07' | System | 21 Apr 2021 21:57:48 |
| User entered '21 Apr 2021 17:57:46' | System | 21 Apr 2021 21:57:48 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '19 Apr 2021 00:01' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '23 Apr 2021 23:59' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered 'Day 264' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[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 (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2021-04-27T18:40:42-04:00', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'd27ca63f-f10e-4884-926c-d701815e7b89' | System | 28 Apr 2021 23:34:31 |
| User entered 'No (N)' | System | 28 Apr 2021 23:34:31 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

Have you been exposed to someone with 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 (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2021-04-27T18:40:48-04:00', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'd27ca63f-f10e-4884-926c-d701815e7b89' | System | 28 Apr 2021 23:34:31 |
| User entered 'No (N)' | System | 28 Apr 2021 23:34:31 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2021-04-27T18:40:52-04:00', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'd27ca63f-f10e-4884-926c-d701815e7b89' | System | 28 Apr 2021 23:34:31 |
| User entered '27 Apr 2021 18:40:52' | System | 28 Apr 2021 23:34:31 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '26 Apr 2021 00:01' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '30 Apr 2021 23:59' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered 'Day 271' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[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 (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2021-05-03T16:06:41-04:00', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'bf7f72cc-971b-41b9-9779-ddbed970dbb9' | System | 03 May 2021 20:06:54 |
| User entered 'No (N)' | System | 03 May 2021 20:06:54 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

Have you been exposed to someone with 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 (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2021-05-03T16:06:47-04:00', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'bf7f72cc-971b-41b9-9779-ddbed970dbb9' | System | 03 May 2021 20:06:54 |
| User entered 'No (N)' | System | 03 May 2021 20:06:54 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2021-05-03T16:06:51-04:00', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: 'bf7f72cc-971b-41b9-9779-ddbed970dbb9' User entered '03 May 2021 16:06:51' | System | 03 May 2021 20:06:54 |
| | System | 03 May 2021 20:06:54 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '03 May 2021 00:01' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '07 May 2021 23:59' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered 'Day 278' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '10 May 2021 00:01' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '14 May 2021 23:59' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered 'Day 285' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '17 May 2021 00:01' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '21 May 2021 23:59' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered 'Day 292' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '24 May 2021 00:01' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '28 May 2021 23:59' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered 'Day 299' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '31 May 2021 00:01' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '04 Jun 2021 23:59' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered 'Day 306' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '07 Jun 2021 00:01' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '11 Jun 2021 23:59' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered 'Day 313' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '14 Jun 2021 00:01' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '18 Jun 2021 23:59' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered 'Day 320' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '21 Jun 2021 00:01' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '25 Jun 2021 23:59' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered 'Day 327' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '28 Jun 2021 00:01' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '02 Jul 2021 23:59' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered 'Day 334' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '05 Jul 2021 00:01' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '09 Jul 2021 23:59' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered 'Day 341' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '12 Jul 2021 00:01' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '16 Jul 2021 23:59' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered 'Day 348' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '19 Jul 2021 00:01' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '23 Jul 2021 23:59' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered 'Day 355' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '26 Jul 2021 00:01' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '30 Jul 2021 23:59' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered 'Day 362' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '02 Aug 2021 00:01' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '06 Aug 2021 23:59' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered 'Day 369' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '09 Aug 2021 00:01' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '13 Aug 2021 23:59' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered 'Day 376' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '16 Aug 2021 00:01' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '20 Aug 2021 23:59' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered 'Day 383' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '23 Aug 2021 00:01' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '27 Aug 2021 23:59' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered 'Day 390' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '30 Aug 2021 00:01' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '03 Sep 2021 23:59' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered 'Day 397' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '06 Sep 2021 00:01' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '10 Sep 2021 23:59' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered 'Day 404' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '13 Sep 2021 00:01' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '17 Sep 2021 23:59' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered 'Day 411' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '20 Sep 2021 00:01' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '24 Sep 2021 23:59' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered 'Day 418' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '27 Sep 2021 00:01' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '01 Oct 2021 23:59' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered 'Day 425' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '04 Oct 2021 00:01' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '08 Oct 2021 23:59' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered 'Day 432' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '11 Oct 2021 00:01' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '15 Oct 2021 23:59' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered 'Day 439' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '18 Oct 2021 00:01' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '22 Oct 2021 23:59' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered 'Day 446' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '25 Oct 2021 00:01' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '29 Oct 2021 23:59' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered 'Day 453' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '01 Nov 2021 00:01' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '05 Nov 2021 23:59' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered 'Day 460' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '08 Nov 2021 00:01' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '12 Nov 2021 23:59' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered 'Day 467' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '15 Nov 2021 00:01' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '19 Nov 2021 23:59' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered 'Day 474' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '22 Nov 2021 00:01' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '26 Nov 2021 23:59' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered 'Day 481' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '29 Nov 2021 00:01' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '03 Dec 2021 23:59' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered 'Day 488' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '06 Dec 2021 00:01' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '10 Dec 2021 23:59' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered 'Day 495' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '13 Dec 2021 00:01' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '17 Dec 2021 23:59' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered 'Day 502' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '20 Dec 2021 00:01' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '24 Dec 2021 23:59' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered 'Day 509' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '27 Dec 2021 00:01' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '31 Dec 2021 23:59' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered 'Day 516' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '03 Jan 2022 00:01' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '07 Jan 2022 23:59' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered 'Day 523' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '10 Jan 2022 00:01' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '14 Jan 2022 23:59' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered 'Day 530' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '17 Jan 2022 00:01' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '21 Jan 2022 23:59' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered 'Day 537' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '24 Jan 2022 00:01' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '28 Jan 2022 23:59' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered 'Day 544' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '31 Jan 2022 00:01' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '04 Feb 2022 23:59' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered 'Day 551' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '07 Feb 2022 00:01' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '11 Feb 2022 23:59' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered 'Day 558' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '14 Feb 2022 00:01' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '18 Feb 2022 23:59' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered 'Day 565' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '21 Feb 2022 00:01' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '25 Feb 2022 23:59' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered 'Day 572' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '28 Feb 2022 00:01' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '04 Mar 2022 23:59' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered 'Day 579' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '07 Mar 2022 00:01' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '11 Mar 2022 23:59' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered 'Day 586' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '14 Mar 2022 00:01' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '18 Mar 2022 23:59' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered 'Day 593' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '21 Mar 2022 00:01' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '25 Mar 2022 23:59' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered 'Day 600' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '28 Mar 2022 00:01' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '01 Apr 2022 23:59' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered 'Day 607' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '04 Apr 2022 00:01' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '08 Apr 2022 23:59' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered 'Day 614' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '11 Apr 2022 00:01' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '15 Apr 2022 23:59' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered 'Day 621' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '18 Apr 2022 00:01' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '22 Apr 2022 23:59' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered 'Day 628' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '25 Apr 2022 00:01' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '29 Apr 2022 23:59' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered 'Day 635' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '02 May 2022 00:01' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '06 May 2022 23:59' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered 'Day 642' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '09 May 2022 00:01' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '13 May 2022 23:59' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered 'Day 649' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '16 May 2022 00:01' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '20 May 2022 23:59' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered 'Day 656' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '23 May 2022 00:01' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '27 May 2022 23:59' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered 'Day 663' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '30 May 2022 00:01' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '03 Jun 2022 23:59' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered 'Day 670' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '06 Jun 2022 00:01' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '10 Jun 2022 23:59' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered 'Day 677' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '13 Jun 2022 00:01' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '17 Jun 2022 23:59' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered 'Day 684' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '20 Jun 2022 00:01' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '24 Jun 2022 23:59' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered 'Day 691' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '27 Jun 2022 00:01' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '01 Jul 2022 23:59' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered 'Day 698' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '04 Jul 2022 00:01' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '08 Jul 2022 23:59' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered 'Day 705' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '11 Jul 2022 00:01' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '15 Jul 2022 23:59' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered 'Day 712' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '18 Jul 2022 00:01' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '22 Jul 2022 23:59' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered 'Day 719' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '25 Jul 2022 00:01' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '29 Jul 2022 23:59' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered 'Day 726' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '01 Aug 2022 00:01' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '05 Aug 2022 23:59' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered 'Day 733' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '08 Aug 2022 00:01' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '12 Aug 2022 23:59' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered 'Day 740' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '15 Aug 2022 00:01' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '19 Aug 2022 23:59' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered 'Day 747' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '22 Aug 2022 00:01' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '26 Aug 2022 23:59' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered 'Day 754' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '29 Aug 2022 00:01' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '02 Sep 2022 23:59' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered 'Day 761' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '05 Sep 2022 00:01' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '09 Sep 2022 23:59' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered 'Day 768' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '12 Sep 2022 00:01' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '16 Sep 2022 23:59' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered 'Day 775' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '19 Sep 2022 00:01' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '23 Sep 2022 23:59' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered 'Day 782' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '26 Sep 2022 00:01' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '30 Sep 2022 23:59' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered 'Day 789' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '03 Oct 2022 00:01' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '07 Oct 2022 23:59' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered 'Day 796' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '10 Oct 2022 00:01' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:25:19

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 16:26:47 |
| Amendment Manager: User entered '14 Oct 2022 23:59' | System | 19 Nov 2020 16:26:47 |

US3402284

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:25:19

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) | 26 Apr 2021 06:39:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2021-03-03T15:50:39-05:00', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '0a066dc8-e651-40c7-baf6-24aab4cbf00a' | System | 03 Mar 2021 20:50:55 |
| User entered 'No (N)' | System | 03 Mar 2021 20:50:55 |

US3402284

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:25:19

[Date & Time of Submission](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 06:39:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77490E0A-DB05-4A43-B20A-65F99CC6C6FA)', Time: '2021-03-03T15:50:51-05:00', User OID: 'PatientReportedOutcome (US3402284)', ODM File OID: '0a066dc8-e651-40c7-baf6-24aab4cbf00a' User entered '03 Mar 2021 15:50:51' | System | 03 Mar 2021 20:50:55 |
| | System | 03 Mar 2021 20:50:55 |

US3402284

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:25:19

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Mar 2021 22:24:41 |
| User closed query 'Was Contact Attempted? = Yes and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is missing. Please review and reconcile.' (Site from System). | (b) (4) | 11 Nov 2020 12:50:03 |
| User opened query 'Was Contact Attempted? = Yes and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is missing. Please review and reconcile.' (Site from System). | System | 11 Nov 2020 12:49:42 |
| User entered 'Yes (Y)' | Tammy Kohn (b) (4) | 03 Nov 2020 15:50:09 |
| | (b) (4) | |

US3402284

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:25:19

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|---|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Mar 2021 22:24:41 |
| User entered '03 Nov 2020' reason for change: New Information | (b) (4) | 11 Nov 2020 12:49:42 |
| User entered '3 Nov 2020' | Traci Hull (b) (4) | 03 Nov 2020 15:50:09 |
| | Tammy Kohn (b) (4) | |
| | (b) (4) | |

US3402284

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:25:19

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Mar 2021 22:24:41 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4) | |
| reason for change: New Information | Traci Hull (b) (4) | 11 Nov 2020 12:50:03 |
| User entered empty; reason for change Data Entry | (b) (4) | |
| Error | Traci Hull (b) (4) | 11 Nov 2020 12:49:42 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4) | |
| | Tammy Kohn (b) (4) | 03 Nov 2020 15:50:09 |
| | (b) (4) | |

US3402284

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:25:19

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Mar 2021 22:24:41 |
| User entered empty. | (b) (4) Tammy Kohn (b) (4) | 03 Nov 2020 15:50:09 |

US3402284

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:25:19

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Mar 2021 22:24:41 |
| User entered 'Yes (Y)' | (b) (4) Tammy Kohn (b) (4) | 03 Nov 2020 15:50:12 |

US3402284

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:25:19

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 18:53:35 |
| User entered 'I' | System | 03 Nov 2020 15:50:12 |

US3402284

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:25:19

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 18:34:46 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| User entered 'Yes (Y)' | (b) (4) Traci Hull (b) (4) | 07 Dec 2020 15:07:34 |

US3402284

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:25:19

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 18:34:46 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| User entered '7 Dec 2020' | Traci Hull (b) (4) | 07 Dec 2020 15:07:34 |

US3402284

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:25:19

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 18:34:46 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| User entered 'Contact Made (CONTACT MADE)' | Traci Hull (b) (4) | 07 Dec 2020 15:07:34 |

US3402284

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:25:19

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 18:34:46 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| User entered empty. | (b) (4) | |
| | Traci Hull (b) (4) | 07 Dec 2020 15:07:34 |
| | (b) (4) | |

US3402284

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:25:19

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 18:34:46 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| User entered 'Yes (Y)' | (b) (4) Traci Hull (b) (4) | 07 Dec 2020 15:07:24 |

US3402284

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:25:19

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 18:34:46 |
| User entered 'I' | System | 07 Dec 2020 15:07:24 |

US3402284

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:25:19

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 18:34:46 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:04:13 |
| User entered 'Yes (Y)' | (b) (4) Tammy Kohn (b) (4) | 06 Jan 2021 17:02:28 |

US3402284

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:25:19

Date of Contact or Contact Attempt (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 18:34:46 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:04:13 |
| User entered '6 Jan 2021' | Tammy Kohn (b) (4) | 06 Jan 2021 17:02:28 |

US3402284

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:25:19

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 18:34:46 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:04:13 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4) Tammy Kohn (b) (4) | 06 Jan 2021 17:02:28 |

US3402284

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:25:19

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 18:34:46 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:04:13 |
| User entered empty. | (b) (4) Tammy Kohn (b) (4) | 06 Jan 2021 17:02:28 |
| | (b) (4) | |

US3402284

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:25:19

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 18:34:46 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| User entered 'Yes (Y)' | (b) (4) Tammy Kohn (b) (4) | 06 Jan 2021 17:02:31 |

US3402284

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:25:19

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 18:34:46 |
| User entered 'I' | System | 06 Jan 2021 17:02:31 |

US3402284

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:25:19

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 18:34:46 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:04:13 |
| User entered 'Yes (Y)' | (b) (4) | 08 Feb 2021 20:22:49 |
| | Traci Hull (b) (4) | |
| | (b) (4) | |

US3402284

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:25:19

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 18:34:46 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:04:13 |
| User entered '8 Feb 2021' | Traci Hull (b) (4) | 08 Feb 2021 20:22:49 |

US3402284

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:25:19

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 18:34:46 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:04:13 |
| User entered 'Contact Made (CONTACT MADE)' | Traci Hull (b) (4) | 08 Feb 2021 20:22:49 |

US3402284

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:25:19

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 18:34:46 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:04:13 |
| User entered empty. | (b) (4) | |
| | Traci Hull (b) (4) | 08 Feb 2021 20:22:49 |
| | (b) (4) | |

US3402284

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:25:19

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 18:34:46 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:04:13 |
| User entered 'Yes (Y)' | (b) (4) Traci Hull (b) (4) | 08 Feb 2021 20:22:55 |

US3402284

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:25:19

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 18:34:46 |
| User entered 'I' | System | 08 Feb 2021 20:22:55 |

US3402284

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:25:19

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 23:54:02 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:04:13 |
| User entered 'Yes (Y)' | (b) (4) | 09 Mar 2021 18:03:47 |
| | Traci Hull (b) (4) | |
| | (b) (4) | |

US3402284

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 23:54:02 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:04:13 |
| User entered '09 Mar 2021' | (b) (4) | |
| | Traci Hull (b) (4) | 09 Mar 2021 18:03:47 |
| | (b) (4) | |

US3402284

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|--------------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 23:54:02 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:04:13 |
| User entered 'Clinic (Clinic)' | (b) (4) | 09 Mar 2021 18:03:47 |
| | Traci Hull (b) (4) | |
| | (b) (4) | |

US3402284

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:25:19

[Folder OID](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 23:54:02 |
| User entered 'VISIT4' | System | 09 Mar 2021 18:03:47 |

US3402284

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:25:19

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 23:54:02 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:04:13 |
| User entered 'No (N)' | (b) (4) Tammy Kohn (b) (4) | 31 Mar 2021 16:54:25 |

US3402284

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:25:19

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 23:54:02 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:04:13 |
| User entered empty. | (b) (4) Tammy Kohn (b) (4) | 31 Mar 2021 16:54:25 |

US3402284

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 23:54:02 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:04:13 |
| User entered empty. | (b) (4) Tammy Kohn (b) (4) | 31 Mar 2021 16:54:25 |

US3402284

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 23:54:02 |
| User entered empty. | System | 31 Mar 2021 16:54:25 |

US3402284

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 23:54:02 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:04:13 |
| User entered empty. | (b) (4) Tammy Kohn (b) (4) | 31 Mar 2021 16:54:25 |

US3402284

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:25:19

[Route of measurement](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 23:54:02 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:04:13 |
| User entered empty. | (b) (4) Tammy Kohn (b) (4) | 31 Mar 2021 16:54:25 |

US3402284

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:25:19

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 23:54:02 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:04:13 |
| User entered empty. | (b) (4) | 31 Mar 2021 16:54:25 |
| | Tammy Kohn (b) (4) | |
| | (b) (4) | |

US3402284

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:25:19

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 23:54:02 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:04:13 |
| User entered empty. | (b) (4) Tammy Kohn (b) (4) | 31 Mar 2021 16:54:25 |

US3402284

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:25:19

[Pulse units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 23:54:02 |
| User entered empty. | System | 31 Mar 2021 16:54:25 |

US3402284

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 23:54:02 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:04:13 |
| User entered empty. | (b) (4) Tammy Kohn (b) (4) | 31 Mar 2021 16:54:25 |

US3402284

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:25:19

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 23:54:02 |
| User entered empty. | System | 31 Mar 2021 16:54:25 |

US3402284

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 23:54:02 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:04:13 |
| User entered empty. | (b) (4) Tammy Kohn (b) (4) | 31 Mar 2021 16:54:25 |

US3402284

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:25:19

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 23:54:02 |
| User entered empty. | System | 31 Mar 2021 16:54:25 |

US3402284

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 23:54:02 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:04:13 |
| User entered empty. | (b) (4) Tammy Kohn (b) (4) | 31 Mar 2021 16:54:25 |

US3402284

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:25:19

[Diastolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 23:54:02 |
| User entered empty. | System | 31 Mar 2021 16:54:25 |

US3402284

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:25:19

Height (derived)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 23:54:02 |
| | | |

US3402284

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:25:19

[Weight \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 23:54:02 |
| | | |

US3402284

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:25:19

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 23:54:02 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:04:13 |
| User entered 'No (N)' | (b) (4) | 09 Mar 2021 18:04:05 |
| | Traci Hull (b) (4) | |
| | (b) (4) | |

US3402284

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:25:19

Date of examination (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 23:54:02 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:04:13 |
| User entered empty. | (b) (4) | 09 Mar 2021 18:04:05 |
| | Traci Hull (b) (4) | |
| | (b) (4) | |

US3402284

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:25:19

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 23:54:02 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:04:13 |
| User entered 'Yes (Y)' | (b) (4) | 09 Mar 2021 18:04:30 |
| | Traci Hull (b) (4) | |
| | (b) (4) | |

US3402284

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:25:19

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 23:54:02 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:04:13 |
| User entered '09 Mar 2021' | (b) (4) | |
| | Traci Hull (b) (4) | 09 Mar 2021 18:04:30 |
| | (b) (4) | |

US3402284

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:25:19

[Collection time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 23:54:02 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:04:13 |
| User entered '11:33' | (b) (4) | 09 Mar 2021 18:04:30 |
| | Traci Hull (b) (4) | |
| | (b) (4) | |

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Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 23:54:02 |
| User entered '09 Mar 2021 11:33' | System | 09 Mar 2021 18:04:30 |

US3402284

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:25:19

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 23:54:02 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:04:13 |
| User entered 'Yes (Y)' | (b) (4) | 09 Mar 2021 18:04:40 |
| | Traci Hull (b) (4) | |
| | (b) (4) | |

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Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:25:19

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 23:54:02 |
| User entered 'I' | System | 09 Mar 2021 18:04:40 |

US3402284

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:25:19

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:04:13 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Traci Hull (b) (4) | 06 Apr 2021 12:54:19 |
| | (b) (4) | |

US3402284

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:25:19

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:04:13 |
| | (b) (4) | |
| User entered '6 Apr 2021' | Traci Hull (b) (4) | 06 Apr 2021 12:54:19 |
| | (b) (4) | |

US3402284

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:25:19

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:04:13 |
| | (b) (4) | |
| User entered 'Contact Made (CONTACT MADE)' | Traci Hull (b) (4) | 06 Apr 2021 12:54:19 |
| | (b) (4) | |

US3402284

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:25:19

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:04:13 |
| | (b) (4) | |
| User entered empty. | Traci Hull (b) (4) | 06 Apr 2021 12:54:19 |
| | (b) (4) | |

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Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:25:19

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:04:13 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Traci Hull (b) (4) | 06 Apr 2021 12:54:09 |
| | (b) (4) | |

US3402284

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:25:19

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 06 Apr 2021 12:54:09 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:25:19

[Date of Contact](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:19 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:36:45 |
| User entered '12 Jan 2021' | Tammy Kohn (b) (4) (b) (4) | 13 Jan 2021 16:42:57 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:25:19

[Time of Contact](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:19 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:36:45 |
| User entered '19:00' | Tammy Kohn (b) (4) (b) (4) | 13 Jan 2021 16:42:57 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:25:19

[Date and Time of Contact \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:19 |
| User entered '12 Jan 2021 19:00' | System | 13 Jan 2021 16:42:57 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:25:19

[Type of Contact](#)

| Audit | User | Time (GMT) |
|--|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:19 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:36:45 |
| User entered 'Clinic Visit - Scheduled (Clinic Visit - Scheduled)' | Tammy Kohn (b) (4) (b) (4) | 13 Jan 2021 16:42:57 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:25:19

[Has the subject reported symptoms of SARS-COV-2?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:19 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:36:45 |
| User entered 'Yes (Y)' | Tammy Kohn (b) (4) (b) (4) | 13 Jan 2021 16:42:57 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:25:19

[Symptom Day](#)

| Audit | User | Time (GMT) |
|------------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| User entered 'Day 1 (Day 1)' | (b) (4) Tammy Kohn (b) (4) | 13 Jan 2021 16:43:28 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:25:19

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered '10 Jan 2021' | Tammy Kohn (b) (4) (b) (4) | 13 Jan 2021 16:43:28 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:25:19

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered 'l' | Tammy Kohn (b) (4) (b) (4) | 13 Jan 2021 16:43:28 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:25:19

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered empty. | Tammy Kohn (b) (4) (b) (4) | 13 Jan 2021 16:43:28 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:25:19

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User entered empty. | System | 13 Jan 2021 16:43:28 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:25:19

[Temperature](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered empty. | Tammy Kohn (b) (4) (b) (4) | 13 Jan 2021 16:43:28 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:25:19

[Chills](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered empty. | Tammy Kohn (b) (4) (b) (4) | 13 Jan 2021 16:43:28 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:25:19

[Cough](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered empty. | Tammy Kohn (b) (4) (b) (4) | 13 Jan 2021 16:43:28 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:25:19

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered empty. | Tammy Kohn (b) (4) (b) (4) | 13 Jan 2021 16:43:28 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:25:19

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered empty. | Tammy Kohn (b) (4) (b) (4) | 13 Jan 2021 16:43:28 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:25:19

[Fatigue](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered empty. | Tammy Kohn (b) (4) (b) (4) | 13 Jan 2021 16:43:28 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:25:19

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered empty. | Tammy Kohn (b) (4) (b) (4) | 13 Jan 2021 16:43:28 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:25:19

[Body Aches](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered empty. | Tammy Kohn (b) (4) (b) (4) | 13 Jan 2021 16:43:28 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:25:19

[Headache](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered empty. | Tammy Kohn (b) (4) (b) (4) | 13 Jan 2021 16:43:28 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:25:19

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered empty. | Tammy Kohn (b) (4) (b) (4) | 13 Jan 2021 16:43:28 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:25:19

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered empty. | Tammy Kohn (b) (4) (b) (4) | 13 Jan 2021 16:43:28 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:25:19

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered empty. | Tammy Kohn (b) (4) (b) (4) | 13 Jan 2021 16:43:28 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:25:19

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered empty. | Tammy Kohn (b) (4) (b) (4) | 13 Jan 2021 16:43:28 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:25:19

[Nausea](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered empty. | Tammy Kohn (b) (4) (b) (4) | 13 Jan 2021 16:43:28 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:25:19

[Vomiting](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered empty. | Tammy Kohn (b) (4) (b) (4) | 13 Jan 2021 16:43:28 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:25:19

[Diarrhea](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered empty. | Tammy Kohn (b) (4) (b) (4) | 13 Jan 2021 16:43:28 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:25:19

[Sore Throat](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered empty. | Tammy Kohn (b) (4) (b) (4) | 13 Jan 2021 16:43:28 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:25:19

[Symptom Day](#)

| Audit | User | Time (GMT) |
|------------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| User entered 'Day 2 (Day 2)' | (b) (4) Tammy Kohn (b) (4) | 13 Jan 2021 16:43:43 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:25:19

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered '11 Jan 2021' | Tammy Kohn (b) (4) (b) (4) | 13 Jan 2021 16:43:43 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:25:19

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered 'l' | Tammy Kohn (b) (4) (b) (4) | 13 Jan 2021 16:43:43 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:25:19

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered empty. | Tammy Kohn (b) (4) (b) (4) | 13 Jan 2021 16:43:43 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:25:19

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User entered empty. | System | 13 Jan 2021 16:43:43 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:25:19

[Temperature](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered empty. | Tammy Kohn (b) (4) (b) (4) | 13 Jan 2021 16:43:43 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:25:19

[Chills](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered empty. | Tammy Kohn (b) (4) (b) (4) | 13 Jan 2021 16:43:43 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:25:19

[Cough](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered empty. | Tammy Kohn (b) (4) (b) (4) | 13 Jan 2021 16:43:43 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:25:19

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered empty. | Tammy Kohn (b) (4) (b) (4) | 13 Jan 2021 16:43:43 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:25:19

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered empty. | Tammy Kohn (b) (4) (b) (4) | 13 Jan 2021 16:43:43 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:25:19

[Fatigue](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered empty. | Tammy Kohn (b) (4) (b) (4) | 13 Jan 2021 16:43:43 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:25:19

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered empty. | Tammy Kohn (b) (4) (b) (4) | 13 Jan 2021 16:43:43 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:25:19

[Body Aches](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered empty. | Tammy Kohn (b) (4) (b) (4) | 13 Jan 2021 16:43:43 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:25:19

[Headache](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered empty. | Tammy Kohn (b) (4) (b) (4) | 13 Jan 2021 16:43:43 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:25:19

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered empty. | Tammy Kohn (b) (4) (b) (4) | 13 Jan 2021 16:43:43 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:25:19

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered empty. | Tammy Kohn (b) (4) (b) (4) | 13 Jan 2021 16:43:43 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:25:19

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered empty. | Tammy Kohn (b) (4) (b) (4) | 13 Jan 2021 16:43:43 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:25:19

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered empty. | Tammy Kohn (b) (4) (b) (4) | 13 Jan 2021 16:43:43 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:25:19

[Nausea](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered empty. | Tammy Kohn (b) (4) (b) (4) | 13 Jan 2021 16:43:43 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:25:19

[Vomiting](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered empty. | Tammy Kohn (b) (4) (b) (4) | 13 Jan 2021 16:43:43 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:25:19

[Diarrhea](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered empty. | Tammy Kohn (b) (4) (b) (4) | 13 Jan 2021 16:43:43 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:25:19

[Sore Throat](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered empty. | Tammy Kohn (b) (4) (b) (4) | 13 Jan 2021 16:43:43 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:25:19

[Symptom Day](#)

| Audit | User | Time (GMT) |
|------------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| User entered 'Day 3 (Day 3)' | (b) (4) Tammy Kohn (b) (4) | 13 Jan 2021 16:46:23 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:25:19

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered '12 Jan 2021' | Tammy Kohn (b) (4) (b) (4) | 13 Jan 2021 16:46:23 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:25:19

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered '0' | Tammy Kohn (b) (4) (b) (4) | 13 Jan 2021 16:46:23 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:25:19

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered '98' | Tammy Kohn (b) (4) (b) (4) | 13 Jan 2021 16:46:23 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:25:19

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User entered '%' | System | 13 Jan 2021 16:46:23 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:25:19

[Temperature](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered '36.5' C | Tammy Kohn (b) (4) (b) (4) | 13 Jan 2021 16:46:23 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:25:19

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered 'None (None)' | Tammy Kohn (b) (4) (b) (4) | 13 Jan 2021 16:46:23 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:25:19

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered 'None (None)' | Tammy Kohn (b) (4) (b) (4) | 13 Jan 2021 16:46:23 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:25:19

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered 'None (None)' | Tammy Kohn (b) (4) (b) (4) | 13 Jan 2021 16:46:23 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:25:19

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered 'None (None)' | Tammy Kohn (b) (4) (b) (4) | 13 Jan 2021 16:46:23 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:25:19

[Fatigue](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered 'None (None)' | Tammy Kohn (b) (4) (b) (4) | 13 Jan 2021 16:46:23 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:25:19

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered 'None (None)' | Tammy Kohn (b) (4) (b) (4) | 13 Jan 2021 16:46:23 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:25:19

[Body Aches](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered 'Mild (Mild)' | Tammy Kohn (b) (4) (b) (4) | 13 Jan 2021 16:46:23 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:25:19

[Headache](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered 'Mild (Mild)' | Tammy Kohn (b) (4) (b) (4) | 13 Jan 2021 16:46:23 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:25:19

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered 'None (None)' | Tammy Kohn (b) (4) (b) (4) | 13 Jan 2021 16:46:23 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:25:19

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered 'None (None)' | Tammy Kohn (b) (4) (b) (4) | 13 Jan 2021 16:46:23 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:25:19

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|------------------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered 'Moderate (Moderate)' | Tammy Kohn (b) (4) (b) (4) | 13 Jan 2021 16:46:23 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:25:19

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered 'None (None)' | Tammy Kohn (b) (4) (b) (4) | 13 Jan 2021 16:46:23 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:25:19

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered 'None (None)' | Tammy Kohn (b) (4) (b) (4) | 13 Jan 2021 16:46:23 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:25:19

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered 'None (None)' | Tammy Kohn (b) (4) (b) (4) | 13 Jan 2021 16:46:23 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:25:19

[Diarrhea](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered 'None (None)' | Tammy Kohn (b) (4) (b) (4) | 13 Jan 2021 16:46:23 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:25:19

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered 'None (None)' | Tammy Kohn (b) (4) (b) (4) | 13 Jan 2021 16:46:23 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:25:19

[Symptom Day](#)

| Audit | User | Time (GMT) |
|------------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| User entered 'Day 4 (Day 4)' | (b) (4) Traci Hull (b) (4) (b) (4) | 19 Jan 2021 21:13:47 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:25:19

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered '13 Jan 2021' | Traci Hull (b) (4) (b) (4) | 19 Jan 2021 21:13:47 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:25:19

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered '0' | Traci Hull (b) (4) (b) (4) | 19 Jan 2021 21:13:47 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:25:19

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered '99' | Traci Hull (b) (4) (b) (4) | 19 Jan 2021 21:13:47 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:25:19

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User entered '%' | System | 19 Jan 2021 21:13:47 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:25:19

[Temperature](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered '97.4' F | Traci Hull (b) (4) (b) (4) | 19 Jan 2021 21:13:47 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:25:19

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered 'None (None)' | Traci Hull (b) (4) (b) (4) | 19 Jan 2021 21:13:47 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:25:19

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered 'None (None)' | Traci Hull (b) (4) (b) (4) | 19 Jan 2021 21:13:47 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:25:19

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered 'None (None)' | Traci Hull (b) (4) (b) (4) | 19 Jan 2021 21:13:47 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:25:19

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered 'None (None)' | Traci Hull (b) (4) (b) (4) | 19 Jan 2021 21:13:47 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:25:19

[Fatigue](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered 'None (None)' | Traci Hull (b) (4) (b) (4) | 19 Jan 2021 21:13:47 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:25:19

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered 'None (None)' | Traci Hull (b) (4) (b) (4) | 19 Jan 2021 21:13:47 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:25:19

[Body Aches](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered 'None (None)' | Traci Hull (b) (4) (b) (4) | 19 Jan 2021 21:13:47 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:25:19

[Headache](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered 'None (None)' | Traci Hull (b) (4) (b) (4) | 19 Jan 2021 21:13:47 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:25:19

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered 'None (None)' | Traci Hull (b) (4) (b) (4) | 19 Jan 2021 21:13:47 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:25:19

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered 'None (None)' | Traci Hull (b) (4) (b) (4) | 19 Jan 2021 21:13:47 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:25:19

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered 'None (None)' | Traci Hull (b) (4) (b) (4) | 19 Jan 2021 21:13:47 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:25:19

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered 'None (None)' | Traci Hull (b) (4) (b) (4) | 19 Jan 2021 21:13:47 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:25:19

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered 'None (None)' | Traci Hull (b) (4) (b) (4) | 19 Jan 2021 21:13:47 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:25:19

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered 'None (None)' | Traci Hull (b) (4) (b) (4) | 19 Jan 2021 21:13:47 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:25:19

[Diarrhea](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered 'None (None)' | Traci Hull (b) (4) (b) (4) | 19 Jan 2021 21:13:47 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:25:19

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered 'None (None)' | Traci Hull (b) (4) (b) (4) | 19 Jan 2021 21:13:47 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:25:19

[Symptom Day](#)

| Audit | User | Time (GMT) |
|------------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| User entered 'Day 5 (Day 5)' | (b) (4) Traci Hull (b) (4) | 19 Jan 2021 21:14:25 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:25:19

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered '14 Jan 2021' | Traci Hull (b) (4) (b) (4) | 19 Jan 2021 21:14:25 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:25:19

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered '0' | Traci Hull (b) (4) (b) (4) | 19 Jan 2021 21:14:25 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:25:19

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered '98' | Traci Hull (b) (4) (b) (4) | 19 Jan 2021 21:14:25 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:25:19

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User entered '%' | System | 19 Jan 2021 21:14:25 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:25:19

[Temperature](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered '97.8' F | Traci Hull (b) (4) (b) (4) | 19 Jan 2021 21:14:25 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:25:19

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered 'None (None)' | Traci Hull (b) (4) (b) (4) | 19 Jan 2021 21:14:25 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:25:19

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered 'None (None)' | Traci Hull (b) (4) (b) (4) | 19 Jan 2021 21:14:25 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:25:19

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered 'None (None)' | Traci Hull (b) (4) (b) (4) | 19 Jan 2021 21:14:25 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:25:19

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered 'None (None)' | Traci Hull (b) (4) (b) (4) | 19 Jan 2021 21:14:25 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:25:19

[Fatigue](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered 'None (None)' | Traci Hull (b) (4) (b) (4) | 19 Jan 2021 21:14:25 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:25:19

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered 'None (None)' | Traci Hull (b) (4) (b) (4) | 19 Jan 2021 21:14:25 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:25:19

[Body Aches](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered 'None (None)' | Traci Hull (b) (4) (b) (4) | 19 Jan 2021 21:14:25 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:25:19

[Headache](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered 'None (None)' | Traci Hull (b) (4) (b) (4) | 19 Jan 2021 21:14:25 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:25:19

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered 'None (None)' | Traci Hull (b) (4) (b) (4) | 19 Jan 2021 21:14:25 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:25:19

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered 'None (None)' | Traci Hull (b) (4) (b) (4) | 19 Jan 2021 21:14:25 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:25:19

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered 'None (None)' | Traci Hull (b) (4) (b) (4) | 19 Jan 2021 21:14:25 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:25:19

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered 'None (None)' | Traci Hull (b) (4) (b) (4) | 19 Jan 2021 21:14:25 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:25:19

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered 'None (None)' | Traci Hull (b) (4) (b) (4) | 19 Jan 2021 21:14:25 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:25:19

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered 'None (None)' | Traci Hull (b) (4) (b) (4) | 19 Jan 2021 21:14:25 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:25:19

[Diarrhea](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered 'None (None)' | Traci Hull (b) (4) (b) (4) | 19 Jan 2021 21:14:25 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:25:19

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered 'None (None)' | Traci Hull (b) (4) (b) (4) | 19 Jan 2021 21:14:25 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:25:19

[Symptom Day](#)

| Audit | User | Time (GMT) |
|------------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| User entered 'Day 6 (Day 6)' | (b) (4) Traci Hull (b) (4) | 19 Jan 2021 21:14:54 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:25:19

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered '15 Jan 2021' | Traci Hull (b) (4) (b) (4) | 19 Jan 2021 21:14:54 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:25:19

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered '0' | Traci Hull (b) (4) (b) (4) | 19 Jan 2021 21:14:54 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:25:19

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered '99' | Traci Hull (b) (4) (b) (4) | 19 Jan 2021 21:14:54 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:25:19

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User entered '%' | System | 19 Jan 2021 21:14:54 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:25:19

[Temperature](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered '96.1' F | Traci Hull (b) (4) (b) (4) | 19 Jan 2021 21:14:54 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:25:19

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered 'None (None)' | Traci Hull (b) (4) (b) (4) | 19 Jan 2021 21:14:54 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:25:19

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered 'None (None)' | Traci Hull (b) (4) (b) (4) | 19 Jan 2021 21:14:54 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:25:19

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered 'None (None)' | Traci Hull (b) (4) (b) (4) | 19 Jan 2021 21:14:54 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:25:19

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered 'None (None)' | Traci Hull (b) (4) (b) (4) | 19 Jan 2021 21:14:54 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:25:19

[Fatigue](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered 'None (None)' | Traci Hull (b) (4) (b) (4) | 19 Jan 2021 21:14:54 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:25:19

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered 'None (None)' | Traci Hull (b) (4) (b) (4) | 19 Jan 2021 21:14:54 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:25:19

[Body Aches](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered 'None (None)' | Traci Hull (b) (4) (b) (4) | 19 Jan 2021 21:14:54 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:25:19

[Headache](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered 'None (None)' | Traci Hull (b) (4) (b) (4) | 19 Jan 2021 21:14:54 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:25:19

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered 'None (None)' | Traci Hull (b) (4) (b) (4) | 19 Jan 2021 21:14:54 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:25:19

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered 'None (None)' | Traci Hull (b) (4) (b) (4) | 19 Jan 2021 21:14:54 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:25:19

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered 'None (None)' | Traci Hull (b) (4) (b) (4) | 19 Jan 2021 21:14:54 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:25:19

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered 'None (None)' | Traci Hull (b) (4) (b) (4) | 19 Jan 2021 21:14:54 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:25:19

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered 'None (None)' | Traci Hull (b) (4) (b) (4) | 19 Jan 2021 21:14:54 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:25:19

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered 'None (None)' | Traci Hull (b) (4) (b) (4) | 19 Jan 2021 21:14:54 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:25:19

[Diarrhea](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered 'None (None)' | Traci Hull (b) (4) (b) (4) | 19 Jan 2021 21:14:54 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:25:19

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered 'None (None)' | Traci Hull (b) (4) (b) (4) | 19 Jan 2021 21:14:54 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:25:19

[Symptom Day](#)

| Audit | User | Time (GMT) |
|------------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| User entered 'Day 7 (Day 7)' | (b) (4) Traci Hull (b) (4) (b) (4) | 19 Jan 2021 21:15:52 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:25:19

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered '16 Jan 2021' | Traci Hull (b) (4) (b) (4) | 19 Jan 2021 21:15:52 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:25:19

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered '0' | Traci Hull (b) (4) (b) (4) | 19 Jan 2021 21:15:52 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:25:19

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered '97' | Traci Hull (b) (4) (b) (4) | 19 Jan 2021 21:15:52 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:25:19

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User entered '%' | System | 19 Jan 2021 21:15:52 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:25:19

[Temperature](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered '96.0' F | Traci Hull (b) (4) (b) (4) | 19 Jan 2021 21:15:52 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:25:19

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered 'None (None)' | Traci Hull (b) (4) (b) (4) | 19 Jan 2021 21:15:52 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:25:19

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered 'None (None)' | Traci Hull (b) (4) (b) (4) | 19 Jan 2021 21:15:52 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:25:19

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered 'None (None)' | Traci Hull (b) (4) (b) (4) | 19 Jan 2021 21:15:52 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:25:19

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered 'None (None)' | Traci Hull (b) (4) (b) (4) | 19 Jan 2021 21:15:52 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:25:19

[Fatigue](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered 'None (None)' | Traci Hull (b) (4) (b) (4) | 19 Jan 2021 21:15:52 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:25:19

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered 'None (None)' | Traci Hull (b) (4) (b) (4) | 19 Jan 2021 21:15:52 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:25:19

[Body Aches](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered 'None (None)' | Traci Hull (b) (4) (b) (4) | 19 Jan 2021 21:15:52 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:25:19

[Headache](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered 'None (None)' | Traci Hull (b) (4) (b) (4) | 19 Jan 2021 21:15:52 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:25:19

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered 'None (None)' | Traci Hull (b) (4) (b) (4) | 19 Jan 2021 21:15:52 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:25:19

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered 'None (None)' | Traci Hull (b) (4) (b) (4) | 19 Jan 2021 21:15:52 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:25:19

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered 'None (None)' | Traci Hull (b) (4) (b) (4) | 19 Jan 2021 21:15:52 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:25:19

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered 'None (None)' | Traci Hull (b) (4) (b) (4) | 19 Jan 2021 21:15:52 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:25:19

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered 'None (None)' | Traci Hull (b) (4) (b) (4) | 19 Jan 2021 21:15:52 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:25:19

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered 'None (None)' | Traci Hull (b) (4) (b) (4) | 19 Jan 2021 21:15:52 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:25:19

[Diarrhea](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered 'None (None)' | Traci Hull (b) (4) (b) (4) | 19 Jan 2021 21:15:52 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:25:19

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered 'None (None)' | Traci Hull (b) (4) (b) (4) | 19 Jan 2021 21:15:52 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:25:19

[Symptom Day](#)

| Audit | User | Time (GMT) |
|------------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| User entered 'Day 8 (Day 8)' | (b) (4) Traci Hull (b) (4) (b) (4) | 19 Jan 2021 21:17:46 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:25:19

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered '17 Jan 2021' | Traci Hull (b) (4) (b) (4) | 19 Jan 2021 21:17:46 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:25:19

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered '0' | Traci Hull (b) (4) (b) (4) | 19 Jan 2021 21:17:46 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:25:19

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered '97' | Traci Hull (b) (4) (b) (4) | 19 Jan 2021 21:17:46 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:25:19

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User entered '%' | System | 19 Jan 2021 21:17:46 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:25:19

[Temperature](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered '96.7' F | Traci Hull (b) (4) (b) (4) | 19 Jan 2021 21:17:46 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:25:19

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered 'None (None)' | Traci Hull (b) (4) (b) (4) | 19 Jan 2021 21:17:46 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:25:19

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered 'None (None)' | Traci Hull (b) (4) (b) (4) | 19 Jan 2021 21:17:46 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:25:19

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered 'None (None)' | Traci Hull (b) (4) (b) (4) | 19 Jan 2021 21:17:46 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:25:19

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered 'None (None)' | Traci Hull (b) (4) (b) (4) | 19 Jan 2021 21:17:46 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:25:19

[Fatigue](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered 'None (None)' | Traci Hull (b) (4) (b) (4) | 19 Jan 2021 21:17:46 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:25:19

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered 'None (None)' | Traci Hull (b) (4) (b) (4) | 19 Jan 2021 21:17:46 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:25:19

[Body Aches](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered 'None (None)' | Traci Hull (b) (4) (b) (4) | 19 Jan 2021 21:17:46 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:25:19

[Headache](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered 'None (None)' | Traci Hull (b) (4) (b) (4) | 19 Jan 2021 21:17:46 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:25:19

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered 'None (None)' | Traci Hull (b) (4) (b) (4) | 19 Jan 2021 21:17:46 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:25:19

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered 'None (None)' | Traci Hull (b) (4) (b) (4) | 19 Jan 2021 21:17:46 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:25:19

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered 'None (None)' | Traci Hull (b) (4) (b) (4) | 19 Jan 2021 21:17:46 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:25:19

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered 'None (None)' | Traci Hull (b) (4) (b) (4) | 19 Jan 2021 21:17:46 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:25:19

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered 'None (None)' | Traci Hull (b) (4) (b) (4) | 19 Jan 2021 21:17:46 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:25:19

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered 'None (None)' | Traci Hull (b) (4) (b) (4) | 19 Jan 2021 21:17:46 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:25:19

[Diarrhea](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered 'None (None)' | Traci Hull (b) (4) (b) (4) | 19 Jan 2021 21:17:46 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:25:19

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered 'None (None)' | Traci Hull (b) (4) (b) (4) | 19 Jan 2021 21:17:46 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:25:19

[Symptom Day](#)

| Audit | User | Time (GMT) |
|------------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| User entered 'Day 9 (Day 9)' | (b) (4) Traci Hull (b) (4) (b) (4) | 19 Jan 2021 21:18:13 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:25:19

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered '18 Jan 2021' | Traci Hull (b) (4) (b) (4) | 19 Jan 2021 21:18:13 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:25:19

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered '0' | Traci Hull (b) (4) (b) (4) | 19 Jan 2021 21:18:13 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:25:19

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered '97' | Traci Hull (b) (4) (b) (4) | 19 Jan 2021 21:18:13 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:25:19

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User entered '%' | System | 19 Jan 2021 21:18:13 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:25:19

[Temperature](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered '98.2' F | Traci Hull (b) (4) (b) (4) | 19 Jan 2021 21:18:13 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:25:19

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered 'None (None)' | Traci Hull (b) (4) (b) (4) | 19 Jan 2021 21:18:13 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:25:19

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered 'None (None)' | Traci Hull (b) (4) (b) (4) | 19 Jan 2021 21:18:13 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:25:19

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered 'None (None)' | Traci Hull (b) (4) (b) (4) | 19 Jan 2021 21:18:13 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:25:19

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered 'None (None)' | Traci Hull (b) (4) (b) (4) | 19 Jan 2021 21:18:13 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:25:19

[Fatigue](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered 'None (None)' | Traci Hull (b) (4) (b) (4) | 19 Jan 2021 21:18:13 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:25:19

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered 'None (None)' | Traci Hull (b) (4) (b) (4) | 19 Jan 2021 21:18:13 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:25:19

[Body Aches](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered 'None (None)' | Traci Hull (b) (4) (b) (4) | 19 Jan 2021 21:18:13 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:25:19

[Headache](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered 'None (None)' | Traci Hull (b) (4) (b) (4) | 19 Jan 2021 21:18:13 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:25:19

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered 'None (None)' | Traci Hull (b) (4) (b) (4) | 19 Jan 2021 21:18:13 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:25:19

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered 'None (None)' | Traci Hull (b) (4) (b) (4) | 19 Jan 2021 21:18:13 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:25:19

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered 'None (None)' | Traci Hull (b) (4) (b) (4) | 19 Jan 2021 21:18:13 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:25:19

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered 'None (None)' | Traci Hull (b) (4) (b) (4) | 19 Jan 2021 21:18:13 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:25:19

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered 'None (None)' | Traci Hull (b) (4) (b) (4) | 19 Jan 2021 21:18:13 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:25:19

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered 'None (None)' | Traci Hull (b) (4) (b) (4) | 19 Jan 2021 21:18:13 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:25:19

[Diarrhea](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered 'None (None)' | Traci Hull (b) (4) (b) (4) | 19 Jan 2021 21:18:13 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:25:19

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered 'None (None)' | Traci Hull (b) (4) (b) (4) | 19 Jan 2021 21:18:13 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:25:19

[Symptom Day](#)

| Audit | User | Time (GMT) |
|--------------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| User entered 'Day 10 (Day 10)' | (b) (4) Traci Hull (b) (4) | 23 Jan 2021 15:38:57 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:25:19

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered '19 Jan 2021' | Traci Hull (b) (4) (b) (4) | 23 Jan 2021 15:38:57 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:25:19

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered '0' | Traci Hull (b) (4) (b) (4) | 23 Jan 2021 15:38:57 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:25:19

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered '99' | Traci Hull (b) (4) (b) (4) | 23 Jan 2021 15:38:57 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:25:19

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User entered '%' | System | 23 Jan 2021 15:38:57 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:25:19

[Temperature](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered '96.2' F | Traci Hull (b) (4) (b) (4) | 23 Jan 2021 15:38:57 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:25:19

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered 'None (None)' | Traci Hull (b) (4) (b) (4) | 23 Jan 2021 15:38:57 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:25:19

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered 'None (None)' | Traci Hull (b) (4) (b) (4) | 23 Jan 2021 15:38:57 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:25:19

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered 'None (None)' | Traci Hull (b) (4) (b) (4) | 23 Jan 2021 15:38:57 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:25:19

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered 'None (None)' | Traci Hull (b) (4) (b) (4) | 23 Jan 2021 15:38:57 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:25:19

[Fatigue](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered 'None (None)' | Traci Hull (b) (4) (b) (4) | 23 Jan 2021 15:38:57 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:25:19

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered 'None (None)' | Traci Hull (b) (4) (b) (4) | 23 Jan 2021 15:38:57 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:25:19

[Body Aches](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered 'None (None)' | Traci Hull (b) (4) (b) (4) | 23 Jan 2021 15:38:57 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:25:19

[Headache](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered 'None (None)' | Traci Hull (b) (4) (b) (4) | 23 Jan 2021 15:38:57 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:25:19

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered 'None (None)' | Traci Hull (b) (4) (b) (4) | 23 Jan 2021 15:38:57 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:25:19

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered 'None (None)' | Traci Hull (b) (4) (b) (4) | 23 Jan 2021 15:38:57 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:25:19

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered 'None (None)' | Traci Hull (b) (4) (b) (4) | 23 Jan 2021 15:38:57 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:25:19

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered 'None (None)' | Traci Hull (b) (4) (b) (4) | 23 Jan 2021 15:38:57 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:25:19

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered 'None (None)' | Traci Hull (b) (4) (b) (4) | 23 Jan 2021 15:38:57 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:25:19

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered 'None (None)' | Traci Hull (b) (4) (b) (4) | 23 Jan 2021 15:38:57 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:25:19

[Diarrhea](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered 'None (None)' | Traci Hull (b) (4) (b) (4) | 23 Jan 2021 15:38:57 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:25:19

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered 'None (None)' | Traci Hull (b) (4) (b) (4) | 23 Jan 2021 15:38:57 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:25:19

[Symptom Day](#)

| Audit | User | Time (GMT) |
|--------------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| User entered 'Day 11 (Day 11)' | (b) (4) Traci Hull (b) (4) | 23 Jan 2021 15:39:44 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:25:19

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered '20 Jan 2021' | Traci Hull (b) (4) (b) (4) | 23 Jan 2021 15:39:44 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:25:19

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered '0' | Traci Hull (b) (4) (b) (4) | 23 Jan 2021 15:39:44 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:25:19

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered '98' | Traci Hull (b) (4) (b) (4) | 23 Jan 2021 15:39:44 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:25:19

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User entered '%' | System | 23 Jan 2021 15:39:44 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:25:19

[Temperature](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered '97.1' F | Traci Hull (b) (4) (b) (4) | 23 Jan 2021 15:39:44 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:25:19

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered 'None (None)' | Traci Hull (b) (4) (b) (4) | 23 Jan 2021 15:39:44 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:25:19

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered 'None (None)' | Traci Hull (b) (4) (b) (4) | 23 Jan 2021 15:39:44 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:25:19

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered 'None (None)' | Traci Hull (b) (4) (b) (4) | 23 Jan 2021 15:39:44 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:25:19

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered 'None (None)' | Traci Hull (b) (4) (b) (4) | 23 Jan 2021 15:39:44 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:25:19

[Fatigue](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered 'None (None)' | Traci Hull (b) (4) (b) (4) | 23 Jan 2021 15:39:44 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:25:19

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered 'None (None)' | Traci Hull (b) (4) (b) (4) | 23 Jan 2021 15:39:44 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:25:19

[Body Aches](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered 'None (None)' | Traci Hull (b) (4) (b) (4) | 23 Jan 2021 15:39:44 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:25:19

[Headache](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered 'None (None)' | Traci Hull (b) (4) (b) (4) | 23 Jan 2021 15:39:44 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:25:19

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered 'None (None)' | Traci Hull (b) (4) (b) (4) | 23 Jan 2021 15:39:44 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:25:19

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered 'None (None)' | Traci Hull (b) (4) (b) (4) | 23 Jan 2021 15:39:44 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:25:19

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered 'None (None)' | Traci Hull (b) (4) (b) (4) | 23 Jan 2021 15:39:44 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:25:19

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered 'None (None)' | Traci Hull (b) (4) (b) (4) | 23 Jan 2021 15:39:44 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:25:19

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered 'None (None)' | Traci Hull (b) (4) (b) (4) | 23 Jan 2021 15:39:44 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:25:19

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered 'None (None)' | Traci Hull (b) (4) (b) (4) | 23 Jan 2021 15:39:44 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:25:19

[Diarrhea](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered 'None (None)' | Traci Hull (b) (4) (b) (4) | 23 Jan 2021 15:39:44 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:25:19

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered 'None (None)' | Traci Hull (b) (4) (b) (4) | 23 Jan 2021 15:39:44 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:25:19

[Symptom Day](#)

| Audit | User | Time (GMT) |
|--------------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| User entered 'Day 12 (Day 12)' | (b) (4) Traci Hull (b) (4) | 23 Jan 2021 15:43:20 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:25:19

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered '21 Jan 2021' | Traci Hull (b) (4) (b) (4) | 23 Jan 2021 15:43:20 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:25:19

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered '0' | Traci Hull (b) (4) (b) (4) | 23 Jan 2021 15:43:20 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:25:19

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered '99' | Traci Hull (b) (4) (b) (4) | 23 Jan 2021 15:43:20 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:25:19

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User entered '%' | System | 23 Jan 2021 15:43:20 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:25:19

[Temperature](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered '97.2' F | Traci Hull (b) (4) (b) (4) | 23 Jan 2021 15:43:20 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:25:19

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered 'None (None)' | Traci Hull (b) (4) (b) (4) | 23 Jan 2021 15:43:20 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:25:19

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered 'None (None)' | Traci Hull (b) (4) (b) (4) | 23 Jan 2021 15:43:20 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:25:19

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered 'None (None)' | Traci Hull (b) (4) (b) (4) | 23 Jan 2021 15:43:20 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:25:19

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered 'None (None)' | Traci Hull (b) (4) (b) (4) | 23 Jan 2021 15:43:20 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:25:19

[Fatigue](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered 'None (None)' | Traci Hull (b) (4) (b) (4) | 23 Jan 2021 15:43:20 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:25:19

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered 'None (None)' | Traci Hull (b) (4) (b) (4) | 23 Jan 2021 15:43:20 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:25:19

[Body Aches](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered 'None (None)' | Traci Hull (b) (4) (b) (4) | 23 Jan 2021 15:43:20 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:25:19

[Headache](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered 'None (None)' | Traci Hull (b) (4) (b) (4) | 23 Jan 2021 15:43:20 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:25:19

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered 'None (None)' | Traci Hull (b) (4) (b) (4) | 23 Jan 2021 15:43:20 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:25:19

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered 'None (None)' | Traci Hull (b) (4) (b) (4) | 23 Jan 2021 15:43:20 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:25:19

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered 'None (None)' | Traci Hull (b) (4) (b) (4) | 23 Jan 2021 15:43:20 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:25:19

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered 'None (None)' | Traci Hull (b) (4) (b) (4) | 23 Jan 2021 15:43:20 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:25:19

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered 'None (None)' | Traci Hull (b) (4) (b) (4) | 23 Jan 2021 15:43:20 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:25:19

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered 'None (None)' | Traci Hull (b) (4) (b) (4) | 23 Jan 2021 15:43:20 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:25:19

[Diarrhea](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered 'None (None)' | Traci Hull (b) (4) (b) (4) | 23 Jan 2021 15:43:20 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:25:19

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:50:04 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:47:49 |
| User entered 'None (None)' | Traci Hull (b) (4) (b) (4) | 23 Jan 2021 15:43:20 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:25:19

[Date of Visit](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:49:57 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:48:00 |
| User entered '12 Jan 2021' | Tammy Kohn (b) (4) (b) (4) | 13 Jan 2021 16:44:28 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:25:19

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:49:57 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:48:00 |
| User entered 'Yes (Y)' | Tammy Kohn (b) (4) (b) (4) | 13 Jan 2021 16:44:28 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:25:19

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:49:57 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:48:00 |
| User entered 'No (N)' | Tammy Kohn (b) (4) (b) (4) | 13 Jan 2021 16:44:28 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:25:19

[Date of Test](#)

| Audit | User | Time (GMT) |
|---|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:49:57 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:48:00 |
| User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated "13-JAN-2021" is recorded under Covid-19 Assessment visit in EDC; however, in PPD portal, it is recorded as "12-JAN-2021" for illness visit. Kindly review the collection date and update as appropriate, else clarify. ' (Site from DM). Query 'Per GCL Lab Reconciliation: Swab: Sample dated "13-JAN-2021" is recorded under Covid-19 Assessment visit in EDC; however, in PPD portal, it is recorded as "12-JAN-2021" for illness visit. Kindly review the collection date and update as appropriate, else clarify. ' answered with 'DATE UPDATED TO THE CORRECT DAY 12 JAN 2021' (Site from DM). | (b) (4), (b) (6) | 16 Feb 2021 05:40:15 |
| User entered '12 Jan 2021' reason for change: Data Entry Error | Tammy Kohn (b) (4) (b) (4) | 15 Feb 2021 15:41:46 |
| User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated "13-JAN-2021" is recorded under Covid-19 Assessment visit in EDC; however, in PPD portal, it is recorded as "12-JAN-2021" for illness visit. Kindly review the collection date and update as appropriate, else clarify. ' (Site from DM). User entered '13 Jan 2021' | (b) (4), (b) (6) | 08 Feb 2021 07:47:25 |
| | Tammy Kohn (b) (4) (b) (4) | 13 Jan 2021 16:44:28 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:25:19

[Type of Test Performed](#)

| Audit | User | Time (GMT) |
|--|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:49:57 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:48:00 |
| User entered 'Nasal Swab (Nasal Swab)' | Tammy Kohn (b) (4) (b) (4) | 13 Jan 2021 16:44:28 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:25:19

[Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:49:57 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:48:00 |
| User entered empty. | Tammy Kohn (b) (4) (b) (4) | 13 Jan 2021 16:44:28 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:25:19

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:49:57 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:48:00 |
| User entered 'No (N)' | Tammy Kohn (b) (4) (b) (4) | 13 Jan 2021 16:44:28 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:25:19

[Lab/ Institution Test Performed](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:49:57 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:48:00 |
| User entered empty. | Tammy Kohn (b) (4) (b) (4) | 13 Jan 2021 16:44:28 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:25:19

[CLIA Certified?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:49:57 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:48:00 |
| User entered empty. | Tammy Kohn (b) (4) (b) (4) | 13 Jan 2021 16:44:28 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:25:19

[COVID-19 Positive \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:49:57 |
| User entered '0' | System | 13 Jan 2021 16:44:28 |

US3402284

Folder: Covid-19 Assessment 12 Jan 2021

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 17:25:19

[Generate Next COVID-19 Assessment](#)

| Audit | User | Time (GMT) |
|---|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 23:49:51 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:48:10 |
| User entered 'No (N)' reason for change: Data Entry Error | Tammy Kohn (b) (4) | 07 Apr 2021 16:11:39 |
| User entered 'Yes (Y)' | (b) (4) Tammy Kohn (b) (4) (b) (4) | 13 Jan 2021 16:43:06 |

US3402284

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 17:25:19

[Visit](#)

| Audit | User | Time (GMT) |
|---|-------------------------------|----------------------|
| User accepted default value 'Day 3 (Day 3)' | Traci Hull (b) (4) (b) (4) | 19 Jan 2021 21:25:59 |

US3402284

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 17:25:19

[Was Saliva Collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:35:17 |
| User entered 'Yes (Y)' | Traci Hull (b) (4) (b) (4) | 19 Jan 2021 21:25:59 |

US3402284

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 17:25:19

[Date of Collection](#)

| Audit | User | Time (GMT) |
|---|--------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 20 Apr 2021 16:35:18 |
| User closed query 'Per Lab Recon: Saliva: Per Preclarus report, it appears there is a collection date mismatch between EDC & PPD GCL records for this "Saliva Day 3" sample, as the "date of collection" is recorded as "14 JAN 2021" in EDC, however the same is recorded as "15 JAN 2021" in PPD GCL. Please confirm the correct sample collection date in response and update in EDC or Preclarus as necessary. Thank you.' (Site from DM). | (b) (4), (b) (6) | 25 Feb 2021 18:10:17 |
| User entered '14 Jan 2021' reason for change: Data Entry Error | Tammy Kohn (b) (4) | 15 Feb 2021 14:46:23 |
| | (b) (4) | |
| Query 'Per Lab Recon: Saliva: Per Preclarus report, it appears there is a collection date mismatch between EDC & PPD GCL records for this "Saliva Day 3" sample, as the "date of collection" is recorded as "14 JAN 2021" in EDC, however the same is recorded as "15 JAN 2021" in PPD GCL. Please confirm the correct sample collection date in response and update in EDC or Preclarus as necessary. Thank you.' answered with 'DATE CORRECTED' (Site from DM). | Tammy Kohn (b) (4) | 15 Feb 2021 14:02:50 |
| | (b) (4) | |
| User entered '15 Jan 2021' reason for change: Data Entry Error | Tammy Kohn (b) (4) | 15 Feb 2021 14:02:32 |
| | (b) (4) | |
| User entered '14 Jan 2021' reason for change: Data Entry Error | Tammy Kohn (b) (4) | 15 Feb 2021 13:50:07 |
| | (b) (4) | |
| User entered '12 Jan 2021' reason for change: Data Entry Error | Tammy Kohn (b) (4) | 15 Feb 2021 13:42:00 |
| | (b) (4) | |
| User opened query 'Per Lab Recon: Saliva: Per Preclarus report, it appears there is a collection date mismatch between EDC & PPD GCL records for this "Saliva Day 3" sample, as the "date of collection" is recorded as "14 JAN 2021" in EDC, however the same is recorded as "15 JAN 2021" in PPD GCL. Please confirm the correct sample collection date in response and update in EDC or Preclarus as necessary. Thank you.' (Site from DM). | (b) (4), (b) (6) | 15 Feb 2021 13:06:57 |

US3402284

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 17:25:19

[Date of Collection](#)

| Audit | User | Time (GMT) |
|---|-------------------------------|----------------------|
| User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 14JAN2021 is recorded under Illness Visit Day 3 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM). | (b) (4), (b) (6) | 15 Feb 2021 13:05:04 |
| Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 14JAN2021 is recorded under Illness Visit Day 3 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' answered with 'THE DATE IS CORRECT AS IS. THE LAB IS PRESENTLY INVESTIGATION THIS ISSUE' (Site from DM). | Tammy Kohn (b) (4) (b) (4) | 04 Feb 2021 13:36:01 |
| User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 14JAN2021 is recorded under Illness Visit Day 3 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM). | (b) (4), (b) (6) | 29 Jan 2021 05:10:24 |
| User entered '14 Jan 2021' | Traci Hull (b) (4) (b) (4) | 19 Jan 2021 21:25:59 |

US3402284

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 17:25:19

[Visit](#)

| Audit | User | Time (GMT) |
|---|-------------------------------|----------------------|
| User accepted default value 'Day 5 (Day 5)' | Traci Hull (b) (4) (b) (4) | 19 Jan 2021 21:25:59 |

US3402284

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 17:25:19

[Was Saliva Collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:35:30 |
| User entered 'Yes (Y)' | Traci Hull (b) (4) (b) (4) | 19 Jan 2021 21:25:59 |

US3402284

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 17:25:19

[Date of Collection](#)

| Audit | User | Time (GMT) |
|---|--------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 20 Apr 2021 16:35:28 |
| User closed query 'Per Lab Recon: Saliva: Per Preclarus report, it appears there is a collection date mismatch between EDC & PPD GCL records for this "Saliva Day 5" sample, as the "date of collection" is recorded as "16 JAN 2021" in EDC, however the same is recorded as "17 JAN 2021" in PPD GCL. Please confirm the correct sample collection date in response and update in EDC or Preclarus as necessary. Thank you. | (b) (4), (b) (6) | 25 Feb 2021 18:10:45 |
| ' (Site from DM). | | |
| User entered '16 Jan 2021' reason for change: Data Entry Error | Tammy Kohn (b) (4) | 15 Feb 2021 14:46:10 |
| | (b) (4) | |
| Query 'Per Lab Recon: Saliva: Per Preclarus report, it appears there is a collection date mismatch between EDC & PPD GCL records for this "Saliva Day 5" sample, as the "date of collection" is recorded as "16 JAN 2021" in EDC, however the same is recorded as "17 JAN 2021" in PPD GCL. Please confirm the correct sample collection date in response and update in EDC or Preclarus as necessary. Thank you. | Tammy Kohn (b) (4) | 15 Feb 2021 14:17:56 |
| | (b) (4) | |
| ' answered with ' CORRECTED DATE' (Site from DM). | | |
| User entered '17 Jan 2021' reason for change: Data Entry Error | Tammy Kohn (b) (4) | 15 Feb 2021 14:17:44 |
| | (b) (4) | |
| User entered '16 Jan 2021' reason for change: Data Entry Error | Tammy Kohn (b) (4) | 15 Feb 2021 13:50:07 |
| | (b) (4) | |
| User entered '14 Jan 2021' reason for change: Data Entry Error | Tammy Kohn (b) (4) | 15 Feb 2021 13:42:00 |
| | (b) (4) | |
| User opened query 'Per Lab Recon: Saliva: Per Preclarus report, it appears there is a collection date mismatch between EDC & PPD GCL records for this "Saliva Day 5" sample, as the "date of collection" is recorded as "16 JAN 2021" in EDC, however the same is recorded as "17 JAN 2021" in PPD GCL. Please confirm the correct sample collection date in response and update in EDC or Preclarus as necessary. Thank you. ' (Site from DM). | (b) (4), (b) (6) | 15 Feb 2021 13:07:31 |

PRODUCTION RELEASE (v12.003
EAB) (1725)

2515 of 3231

US3402284

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 17:25:19

[Date of Collection](#)

| Audit | User | Time (GMT) |
|---|-------------------------------|----------------------|
| User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 16JAN2021 is recorded under Illness Visit Day 5 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM). | (b) (4), (b) (6) | 15 Feb 2021 13:05:09 |
| Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 16JAN2021 is recorded under Illness Visit Day 5 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' answered with 'THE DATE IS CORRECT AS IS. THE LAB IS PRESENTLY INVESTIGATION THIS ISSUE' (Site from DM). | Tammy Kohn (b) (4) (b) (4) | 04 Feb 2021 13:36:08 |
| User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 16JAN2021 is recorded under Illness Visit Day 5 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM). | (b) (4), (b) (6) | 29 Jan 2021 05:10:33 |
| User entered '16 Jan 2021' | Traci Hull (b) (4) (b) (4) | 19 Jan 2021 21:25:59 |

US3402284

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 17:25:19

[Visit](#)

| Audit | User | Time (GMT) |
|---|-------------------------------|----------------------|
| User accepted default value 'Day 7 (Day 7)' | Traci Hull (b) (4) (b) (4) | 19 Jan 2021 21:25:59 |

US3402284

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 17:25:19

[Was Saliva Collected?](#)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 20 Apr 2021 16:35:36 |
| User entered 'NA (COVID-19 Negative) (NA)' reason for change: Data Entry Error | Tammy Kohn (b) (4) | 07 Apr 2021 19:46:23 |
| | (b) (4) | |
| User entered 'No (N)' reason for change: Data Entry Error | Tammy Kohn (b) (4) | 07 Apr 2021 19:46:17 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Traci Hull (b) (4) | 19 Jan 2021 21:25:59 |
| | (b) (4) | |

US3402284

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 17:25:19

[Date of Collection](#)

| Audit | User | Time (GMT) |
|---|--------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 20 Apr 2021 16:35:37 |
| User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 18JAN2021 is recorded under Illness Visit Day 7 in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM). | (b) (4), (b) (6) | 12 Apr 2021 06:18:57 |
| Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 18JAN2021 is recorded under Illness Visit Day 7 in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' answered with 'CONFIRMED NEGATIVE' (Site from DM). | Tammy Kohn (b) (4) | 07 Apr 2021 19:46:37 |
| | (b) (4) | |
| User entered empty; reason for change Data Entry Error | Tammy Kohn (b) (4) | 07 Apr 2021 19:46:17 |
| | (b) (4) | |
| User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 18JAN2021 is recorded under Illness Visit Day 7 in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM). | (b) (4), (b) (6) | 22 Mar 2021 07:45:30 |

US3402284

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 17:25:19

[Date of Collection](#)

| Audit | User | Time (GMT) |
|--|-------------------------------|----------------------|
| User closed query 'Per GCL Lab Recon: SALIVA: Per Preclarus report, there is no record of this DAY 7 Saliva sample with collection date of 18 JAN 2021 under Subject ID US3402284 in PPD GCL , please kindly review and update the missing sample data in Preclarus PPD portal. If there is any SUBJECT ID entry error or ID mismatch during collection or shipping process, and kindly provide the correct subject ID in the response to which these SALIVA samples actually belongs. Thank you.' (Site from DM). | (b) (4), (b) (6) | 25 Feb 2021 18:10:54 |
| Query 'Per GCL Lab Recon: SALIVA: Per Preclarus report, there is no record of this DAY 7 Saliva sample with collection date of 18 JAN 2021 under Subject ID US3402284 in PPD GCL , please kindly review and update the missing sample data in Preclarus PPD portal. If there is any SUBJECT ID entry error or ID mismatch during collection or shipping process, and kindly provide the correct subject ID in the response to which these SALIVA samples actually belongs. Thank you.' answered with 'DATE IS CORRECT REQUISITION PAPERWORK HAS BEEN SENT TO PPD TO HAVE THIS CORRECTED' (Site from DM). | Tammy Kohn (b) (4) (b) (4) | 15 Feb 2021 14:42:46 |
| User entered '18 Jan 2021' reason for change: Data Entry Error | Tammy Kohn (b) (4) (b) (4) | 15 Feb 2021 13:50:07 |
| User entered '16 Jan 2021' reason for change: Data Entry Error | Tammy Kohn (b) (4) (b) (4) | 15 Feb 2021 13:42:00 |
| User opened query 'Per GCL Lab Recon: SALIVA: Per Preclarus report, there is no record of this DAY 7 Saliva sample with collection date of 18 JAN 2021 under Subject ID US3402284 in PPD GCL , please kindly review and update the missing sample data in Preclarus PPD portal. If there is any SUBJECT ID entry error or ID mismatch during collection or shipping process, and kindly provide the correct subject ID in the response to which these SALIVA samples actually belongs. Thank you.' (Site from DM). | (b) (4), (b) (6) | 15 Feb 2021 13:12:36 |

US3402284

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 17:25:19

[Date of Collection](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Query 'Per GCL Lab Recon: SALIVA: Per Preclarus report, there is no record of this DAY 7 Saliva sample with collection date of 18 JAN 2021 under Subject ID US3402284 in PPD GCL , please kindly review and update the missing sample data in Preclarus PPD portal. If there is any SUBJECT ID entry error or ID mismatch during collection or shipping process, and kindly provide the correct subject ID in the response to which these SALIVA samples actually belongs, and if applicable kindly send a DCF to update in Preclarus PPD, as there is no record of this subject ID record per Preclarus report. Thank you.' canceled (Site from DM). | (b) (4), (b) (6) | 15 Feb 2021 13:12:20 |
| User opened query 'Per GCL Lab Recon: SALIVA: Per Preclarus report, there is no record of this DAY 7 Saliva sample with collection date of 18 JAN 2021 under Subject ID US3402284 in PPD GCL , please kindly review and update the missing sample data in Preclarus PPD portal. If there is any SUBJECT ID entry error or ID mismatch during collection or shipping process, and kindly provide the correct subject ID in the response to which these SALIVA samples actually belongs, and if applicable kindly send a DCF to update in Preclarus PPD, as there is no record of this subject ID record per Preclarus report. Thank you.' (Site from DM). | (b) (4), (b) (6) | 15 Feb 2021 13:10:16 |
| User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 18JAN2021 is recorded under Illness Visit Day 7 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM). | (b) (4), (b) (6) | 15 Feb 2021 13:05:14 |

US3402284

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 17:25:19

[Date of Collection](#)

| Audit | User | Time (GMT) |
|--|-------------------------------|----------------------|
| Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 18JAN2021 is recorded under Illness Visit Day 7 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' answered with 'THE DATE IS CORRECT AS IS. THE LAB IS PRESENTLY INVESTIGATION THIS ISSUE' (Site from DM). | Tammy Kohn (b) (4) (b) (4) | 04 Feb 2021 13:36:15 |
| User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 18JAN2021 is recorded under Illness Visit Day 7 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM). | (b) (4), (b) (6) | 29 Jan 2021 05:10:57 |
| User entered '18 Jan 2021' | Traci Hull (b) (4) (b) (4) | 19 Jan 2021 21:25:59 |

US3402284

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 17:25:19

[Visit](#)

| Audit | User | Time (GMT) |
|---|-------------------------------|----------------------|
| User accepted default value 'Day 9 (Day 9)' | Traci Hull (b) (4) (b) (4) | 19 Jan 2021 21:25:59 |

US3402284

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 17:25:19

[Was Saliva Collected?](#)

| Audit | User | Time (GMT) |
|---|--------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 20 Apr 2021 16:35:45 |
| | | |
| User entered 'No (N)' reason for change: New Information | Tammy Kohn (b) (4) | 15 Feb 2021 14:46:34 |
| | (b) (4) | |
| User entered 'Yes (Y)' reason for change: New Information | Traci Hull (b) (4) | 23 Jan 2021 15:46:24 |
| | (b) (4) | |
| User entered 'No (N)' | Traci Hull (b) (4) | 19 Jan 2021 21:25:59 |
| | (b) (4) | |

US3402284

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 17:25:19

[Date of Collection](#)

| Audit | User | Time (GMT) |
|---|--------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 20 Apr 2021 16:35:45 |
| User closed query 'Per GCL Lab Recon: Saliva: Per previous response "as this sample was never collected," please kindly remove the sample collection date as well in this field. Thank you.' (Site from DM). | (b) (4), (b) (6) | 10 Mar 2021 07:24:28 |
| Query 'Per GCL Lab Recon: Saliva: Per previous response "as this sample was never collected," please kindly remove the sample collection date as well in this field. Thank you.' answered with 'DATE REMOVED' (Site from DM). | Tammy Kohn (b) (4) | 09 Mar 2021 14:41:48 |
| | (b) (4) | |
| User entered empty; reason for change New Information | Tammy Kohn (b) (4) | 09 Mar 2021 14:41:40 |
| | (b) (4) | |
| User opened query 'Per GCL Lab Recon: Saliva: Per previous response "as this sample was never collected," please kindly remove the sample collection date as well in this field. Thank you.' (Site from DM). | (b) (4), (b) (6) | 25 Feb 2021 18:12:37 |
| | | |
| User closed query 'Per GCL Lab Recon: SALIVA: Per Preclarus report, there is no record of this "DAY 9 Saliva" sample with collection date of 20 JAN 2021 under Subject ID US3402284 in PPD GCL , please kindly review and update the missing sample data in Preclarus PPD portal. If there is any SUBJECT ID entry error or ID mismatch during collection or shipping process, kindly provide the correct subject ID in the response to which these SALIVA sample actually belongs. Thank you.' (Site from DM). | (b) (4), (b) (6) | 25 Feb 2021 18:11:08 |
| | | |

US3402284

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 17:25:19

[Date of Collection](#)

| Audit | User | Time (GMT) |
|---|-------------------------------|----------------------|
| Query 'Per GCL Lab Recon: SALIVA: Per Preclarus report, there is no record of this "DAY 9 Saliva" sample with collection date of 20 JAN 2021 under Subject ID US3402284 in PPD GCL , please kindly review and update the missing sample data in Preclarus PPD portal. If there is any SUBJECT ID entry error or ID mismatch during collection or shipping process, kindly provide the correct subject ID in the response to which these SALIVA sample actually belongs. Thank you.' answered with 'THIS SAMPLE WAS NEVER COLLECTED' (Site from DM). | Tammy Kohn (b) (4) (b) (4) | 15 Feb 2021 14:46:56 |
| User entered '20 Jan 2021' reason for change: New Information | Tammy Kohn (b) (4) (b) (4) | 15 Feb 2021 14:05:56 |
| User entered '21 Jan 2021' reason for change: New Information | Tammy Kohn (b) (4) (b) (4) | 15 Feb 2021 14:03:42 |
| User entered '20 Jan 2021' reason for change: New Information | Tammy Kohn (b) (4) (b) (4) | 15 Feb 2021 13:50:07 |
| User entered '18 Jan 2021' reason for change: New Information | Tammy Kohn (b) (4) (b) (4) | 15 Feb 2021 13:42:00 |
| User opened query 'Per GCL Lab Recon: SALIVA: Per Preclarus report, there is no record of this "DAY 9 Saliva" sample with collection date of 20 JAN 2021 under Subject ID US3402284 in PPD GCL , please kindly review and update the missing sample data in Preclarus PPD portal. If there is any SUBJECT ID entry error or ID mismatch during collection or shipping process, kindly provide the correct subject ID in the response to which these SALIVA sample actually belongs. Thank you.' (Site from DM). | (b) (4), (b) (6) (b) (4) | 15 Feb 2021 13:11:36 |
| User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 20JAN2021 is recorded under Illness Visit Day 9 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM). | (b) (4), (b) (6) (b) (4) | 15 Feb 2021 13:05:20 |

US3402284

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 17:25:19

[Date of Collection](#)

| Audit | User | Time (GMT) |
|--|-------------------------------|----------------------|
| Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 20JAN2021 is recorded under Illness Visit Day 9 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' answered with 'THE DATE IS CORRECT AS IS. THE LAB IS PRESENTLY INVESTIGATION THIS ISSUE' (Site from DM). | Tammy Kohn (b) (4) (b) (4) | 04 Feb 2021 13:36:23 |
| User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 20JAN2021 is recorded under Illness Visit Day 9 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM). | (b) (4), (b) (6) | 29 Jan 2021 05:11:06 |
| User entered '20 Jan 2021' reason for change: New Information | Traci Hull (b) (4) (b) (4) | 23 Jan 2021 15:46:24 |
| User entered empty. | Traci Hull (b) (4) (b) (4) | 19 Jan 2021 21:25:59 |

US3402284

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 17:25:19

[Visit](#)

| Audit | User | Time (GMT) |
|---|-------------------------------|----------------------|
| User accepted default value 'Day 14 (Day 14)' | Traci Hull (b) (4) (b) (4) | 19 Jan 2021 21:25:59 |

US3402284

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 17:25:19

[Was Saliva Collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:35:45 |
| User entered 'No (N)' | Traci Hull (b) (4) (b) (4) | 19 Jan 2021 21:25:59 |

US3402284

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 17:25:19

[Date of Collection](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:35:45 |
| User entered empty. | Traci Hull (b) (4) (b) (4) | 19 Jan 2021 21:25:59 |

US3402284

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 17:25:19

[Visit](#)

| Audit | User | Time (GMT) |
|---|-------------------------------|----------------------|
| User accepted default value 'Day 21 (Day 21)' | Traci Hull (b) (4) (b) (4) | 19 Jan 2021 21:25:59 |

US3402284

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 17:25:19

[Was Saliva Collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:35:45 |
| User entered 'No (N)' | Traci Hull (b) (4) (b) (4) | 19 Jan 2021 21:25:59 |

US3402284

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 17:25:19

[Date of Collection](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:35:45 |
| User entered empty. | Traci Hull (b) (4) (b) (4) | 19 Jan 2021 21:25:59 |

US3402284

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 17:25:19

[Visit](#)

| Audit | User | Time (GMT) |
|---|-------------------------------|----------------------|
| User accepted default value 'Day 28 (Day 28)' | Traci Hull (b) (4) (b) (4) | 19 Jan 2021 21:25:59 |

US3402284

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 17:25:19

[Was Saliva Collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:35:45 |
| User entered 'No (N)' | Traci Hull (b) (4) (b) (4) | 19 Jan 2021 21:25:59 |

US3402284

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 17:25:19

[Date of Collection](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:35:45 |
| User entered empty. | Traci Hull (b) (4) (b) (4) | 19 Jan 2021 21:25:59 |

US3402284

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:25:19

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 15:33:52 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:34:04 |
| User entered 'Yes (Y)' | Traci Hull (b) (4) (b) (4) | 19 Jan 2021 21:20:26 |

US3402284

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 15:33:52 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:34:04 |
| User entered '12 Jan 2021' | Traci Hull (b) (4) (b) (4) | 19 Jan 2021 21:20:26 |

US3402284

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|--------------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 15:33:52 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:34:04 |
| User entered 'Clinic (Clinic)' | Traci Hull (b) (4) (b) (4) | 19 Jan 2021 21:20:26 |

US3402284

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:25:19

[Folder OID](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 15:33:52 |
| User entered 'SICKD1' | System | 19 Jan 2021 21:20:26 |

US3402284

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:25:19

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 15:33:52 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:34:25 |
| User entered 'Yes (Y)' | Traci Hull (b) (4) (b) (4) | 19 Jan 2021 21:21:46 |

US3402284

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:25:19

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 15:33:52 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:34:25 |
| User entered '12 Jan 2021' | Traci Hull (b) (4) (b) (4) | 19 Jan 2021 21:21:46 |

US3402284

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 15:33:52 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:34:25 |
| User entered '12:20' | Traci Hull (b) (4) (b) (4) | 19 Jan 2021 21:21:46 |

US3402284

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 15:33:52 |
| User entered '12 Jan 2021 12:20' | System | 19 Jan 2021 21:21:46 |

US3402284

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 15:33:52 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:34:25 |
| User entered missing code ND - Not Done. | Traci Hull (b) (4) | 19 Jan 2021 21:21:46 |
| DataPoint set to visible. | (b) (4) System | 19 Jan 2021 21:20:26 |

US3402284

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 15:33:52 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:34:25 |
| User entered missing code ND - Not Done. | Traci Hull (b) (4) | 19 Jan 2021 21:21:46 |
| DataPoint set to visible. | (b) (4) System | 19 Jan 2021 21:20:26 |

US3402284

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 15:33:52 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:34:25 |
| User entered '36.5' C | Traci Hull (b) (4) (b) (4) | 19 Jan 2021 21:21:46 |

US3402284

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:25:19

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 15:33:52 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 20 Apr 2021 16:34:25 |
| User entered 'Oral (Oral)' | Traci Hull (b) (4) | 19 Jan 2021 21:21:46 |
| | (b) (4) | |

US3402284

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:25:19

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 15:33:52 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:34:25 |
| User entered empty. | Traci Hull (b) (4) (b) (4) | 19 Jan 2021 21:21:46 |

US3402284

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:25:19

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 15:33:52 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:34:25 |
| User entered '93' | Traci Hull (b) (4) (b) (4) | 19 Jan 2021 21:21:46 |

US3402284

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:25:19

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 15:33:52 |
| User entered 'bpm' | System | 19 Jan 2021 21:21:46 |

US3402284

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 15:33:52 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) | 20 Apr 2021 16:34:25 |
| User entered '14' | Traci Hull (b) (4) | 19 Jan 2021 21:21:46 |

US3402284

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:25:19

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 15:33:52 |
| User entered 'breaths/min' | System | 19 Jan 2021 21:21:46 |

US3402284

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 15:33:52 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:34:25 |
| User entered '160' | Traci Hull (b) (4) (b) (4) | 19 Jan 2021 21:21:46 |

US3402284

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:25:19

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 15:33:52 |
| User entered 'mmHg' | System | 19 Jan 2021 21:21:46 |

US3402284

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 15:33:52 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:34:25 |
| User entered '92' | Traci Hull (b) (4) (b) (4) | 19 Jan 2021 21:21:46 |

US3402284

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:25:19

[Diastolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 15:33:52 |
| User entered 'mmHg' | System | 19 Jan 2021 21:21:46 |

US3402284

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:25:19

[Height \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 15:33:52 |
| | | |

US3402284

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:25:19

[Weight \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 15:33:52 |
| | | |

US3402284

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:25:19

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 15:33:52 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:34:31 |
| User entered 'Yes (Y)' | Traci Hull (b) (4) (b) (4) | 19 Jan 2021 21:22:32 |

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Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:25:19

Date of examination (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 15:33:52 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:34:31 |
| User entered '12 Jan 2021' | Traci Hull (b) (4) (b) (4) | 19 Jan 2021 21:22:32 |

US3402284

Folder: Illness Visit Day 1 (1)

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

Generated On: 09 Jun 2021 17:25:19

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 15:33:52 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:34:36 |
| User entered 'Yes (Y)' | Traci Hull (b) (4) (b) (4) | 19 Jan 2021 21:23:02 |

US3402284

Folder: Illness Visit Day 1 (1)

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

Generated On: 09 Jun 2021 17:25:19

[Date of Collection](#)

| Audit | User | Time (GMT) |
|---|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 15:33:52 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 16:34:36 |
| User closed query 'Per Lab Recon: SARS-COV2: Sample dated 12 JAN 2021 is missing in PPD GCL records, please kindly review the preclarus and update the PPD GCL with missing sample data. Please review if the sample has been shipped by providing in response the Accession number, Tracking number & shipping date, as this helps to track the sample with the details provided. Please kindly also review if site has to scan in barcodes through preclarus, so that the data reflects in PPD GCL records. Thank you.' (Site from DM). | (b) (4), (b) (6) | 10 Feb 2021 10:38:09 |
| Query 'Per Lab Recon: SARS-COV2: Sample dated 12 JAN 2021 is missing in PPD GCL records, please kindly review the preclarus and update the PPD GCL with missing sample data. Please review if the sample has been shipped by providing in response the Accession number, Tracking number & shipping date, as this helps to track the sample with the details provided. Please kindly also review if site has to scan in barcodes through preclarus, so that the data reflects in PPD GCL records. Thank you.' answered with 'THIS IS BEING HANDLED THROUGH OUR LAB' (Site from DM). | Tammy Kohn (b) (4) (b) (4) | 04 Feb 2021 13:31:59 |
| User opened query 'Per Lab Recon: SARS-COV2: Sample dated 12 JAN 2021 is missing in PPD GCL records, please kindly review the preclarus and update the PPD GCL with missing sample data. Please review if the sample has been shipped by providing in response the Accession number, Tracking number & shipping date, as this helps to track the sample with the details provided. Please kindly also review if site has to scan in barcodes through preclarus, so that the data reflects in PPD GCL records. Thank you.' (Site from DM). | (b) (4), (b) (6) | 29 Jan 2021 04:37:40 |
| User entered '12 Jan 2021' | Traci Hull (b) (4) (b) (4) | 19 Jan 2021 21:23:02 |

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3402284

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

Form: Visit Date

Generated On: 09 Jun 2021 17:25:19

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 23:52:25 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| User entered 'Yes (Y)' | (b) (4) | 29 Jan 2021 13:22:40 |
| | Traci Hull (b) (4) | |
| | (b) (4) | |

US3402284

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

Form: Visit Date

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 23:52:25 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| User entered '29 Jan 2021' | (b) (4) | |
| | Traci Hull (b) (4) | 29 Jan 2021 13:22:40 |
| | (b) (4) | |

US3402284

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

Form: Visit Date

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|--------------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 23:52:25 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| User entered 'Clinic (Clinic)' | (b) (4) Traci Hull (b) (4) (b) (4) | 29 Jan 2021 13:22:40 |

US3402284

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

Form: Visit Date

Generated On: 09 Jun 2021 17:25:19

[Folder OID](#)

| Audit | User | Time (GMT) |
|------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 23:52:25 |
| User entered 'UNBLND_DECIDE' | System | 29 Jan 2021 13:22:40 |

US3402284

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

Form: Unblinding

Generated On: 09 Jun 2021 17:25:19

[Date of updated informed consent \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 23:52:25 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| User entered '06 Jan 2021' | (b) (4) | 29 Jan 2021 13:23:37 |
| | Traci Hull (b) (4) | |
| | (b) (4) | |

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

Form: Unblinding

Generated On: 09 Jun 2021 17:25:19

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

| Audit | User | Time (GMT) |
|--|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 23:52:25 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| User entered '0' | (b) (4) Tammy Kohn (b) (4) | 09 Apr 2021 13:33:39 |
| Amendment Manager inserted this DataPoint. | (b) (4) System | 06 Mar 2021 11:58:01 |

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

Form: Unblinding

Generated On: 09 Jun 2021 17:25:19

[Was the participant unblinded?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 23:52:25 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| User entered 'Yes (Y)' | (b) (4) | 29 Jan 2021 13:23:37 |
| | Traci Hull (b) (4) | |
| | (b) (4) | |

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

Form: Unblinding

Generated On: 09 Jun 2021 17:25:19

[Under what version of the Protocol was the Participant unblinded?](#)

| Audit | User | Time (GMT) |
|--|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 23:52:25 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| 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) | 10 Apr 2021 06:03:27 |
| 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 'data updated' (Site from DM). | Tammy Kohn (b) (4) (b) (4) | 09 Apr 2021 13:33:42 |
| User entered 'Amendment 6 or later (Amendment 6 or later)' | Tammy Kohn (b) (4) (b) (4) | 09 Apr 2021 13:33:39 |
| 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 15:51:07 |
| Amendment Manager inserted this DataPoint. | System | 06 Mar 2021 11:58:01 |

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

Form: Unblinding

Generated On: 09 Jun 2021 17:25:19

Date of unblinding (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 23:52:25 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| User entered '29 Jan 2021' | (b) (4) | |
| | Traci Hull (b) (4) | 29 Jan 2021 13:23:37 |
| | (b) (4) | |

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

Form: Unblinding

Generated On: 09 Jun 2021 17:25:19

[Participant randomization assignment](#)

| Audit | User | Time (GMT) |
|--------------------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 23:52:25 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| User entered 'mRNA-1273 (mRNA-1273)' | (b) (4) Traci Hull (b) (4) | 29 Jan 2021 13:23:37 |

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

Form: Unblinding

Generated On: 09 Jun 2021 17:25:19

[Actual Dose 1](#)

| Audit | User | Time (GMT) |
|--------------------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 23:52:25 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| User entered 'mRNA-1273 (mRNA-1273)' | (b) (4) Traci Hull (b) (4) | 29 Jan 2021 13:23:37 |

US3402284

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

Form: Unblinding

Generated On: 09 Jun 2021 17:25:19

[Actual Dose 2](#)

| Audit | User | Time (GMT) |
|--------------------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 23:52:25 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| User entered 'mRNA-1273 (mRNA-1273)' | (b) (4) Traci Hull (b) (4) | 29 Jan 2021 13:23:37 |

US3402284

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

Form: Unblinding

Generated On: 09 Jun 2021 17:25:19

[Will participant receive mRNA-1273?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 23:52:25 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| User entered 'No (N)' | (b) (4) | 29 Jan 2021 13:23:37 |
| | Traci Hull (b) (4) | |
| | (b) (4) | |

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

Form: Unblinding

Generated On: 09 Jun 2021 17:25:19

[Placebo Only Flag](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 23:52:25 |
| User entered empty. | System | 29 Jan 2021 13:23:37 |

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

Form: Unblinding

Generated On: 09 Jun 2021 17:25:19

[Continuing with mRNA-1273](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 23:52:25 |
| User entered empty. | System | 29 Jan 2021 13:23:37 |

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:25:19

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 23:52:25 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| User entered 'Yes (Y)' | (b) (4) | 29 Jan 2021 13:23:48 |
| | Traci Hull (b) (4) | |
| | (b) (4) | |

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:25:19

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 23:52:25 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| User entered '29 Jan 2021' | (b) (4) | |
| | Traci Hull (b) (4) | 29 Jan 2021 13:23:48 |
| | (b) (4) | |

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:25:19

[Collection time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 23:52:25 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| User entered '07:45' | (b) (4) | 29 Jan 2021 13:23:48 |
| | Traci Hull (b) (4) | |
| | (b) (4) | |

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 23:52:25 |
| User entered '29 Jan 2021 07:45' | System | 29 Jan 2021 13:23:48 |

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:25:19

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 23:52:25 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| User entered 'Yes (Y)' | (b) (4) | 29 Jan 2021 13:24:01 |
| | Traci Hull (b) (4) | |
| | (b) (4) | |

US3402284

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 23:52:25 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| User entered '29 Jan 2021' | (b) (4) | |
| | Traci Hull (b) (4) | 29 Jan 2021 13:24:01 |
| | (b) (4) | |

US3402284

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:25:19

[Collection time \(00:00 - 23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 23:52:25 |
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| User entered '07:41' | (b) (4) | 29 Jan 2021 13:24:01 |
| | Traci Hull (b) (4) | |
| | (b) (4) | |

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 23:52:25 |
| User entered '29 Jan 2021 07:41' | System | 29 Jan 2021 13:24:01 |

US3402284

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 17:25:19

[Did the participant experience any adverse events?](#)

| Audit | User | Time (GMT) |
|--|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 06:32:45 |
| User closed query 'Per CDM re-query: Thank you for adding the events. However the AE END DATE doesn't correspond to eDiary end date for MUSCLE ACHE (Day 14: AUG 21), FATIGUE (Day 14: 21 AUG). Please review and update as appropriate else clarify. ' (Site from DM). | (b) (4), (b) (6) | 13 Apr 2021 09:57:50 |
| Query 'Per CDM re-query: Thank you for adding the events. However the AE END DATE doesn't correspond to eDiary end date for MUSCLE ACHE (Day 14: AUG 21), FATIGUE (Day 14: 21 AUG). Please review and update as appropriate else clarify. ' answered with 'updated end dates.' (Site from DM). | Tammy Kohn (b) (4) (b) (4) | 08 Apr 2021 15:37:50 |
| User closed query 'Per DM CLR: Please note, Per Diary Dose 2 Record, the following symptoms persist beyond Day 7: JOINT ACHES (start date: Day 1; end date: Day 18); MUSCLE ACHES (Day 2-23). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification.' (Site from DM). | (b) (4), (b) (6) | 08 Apr 2021 10:08:14 |
| User closed query 'Per DM CLR: Please note, Per Diary Dose 1 Record, the following symptoms persist beyond Day 7 : FATIGUE (start date: Day 1; end date: Day 14); JOINT ACHES (Day 1-12); MUSCLE ACHES (Day 1-14). Review if these should be recorded as Solicited Adverse Reactions per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification.' (Site from DM). | (b) (4), (b) (6) | 08 Apr 2021 10:06:30 |
| User opened query 'Per CDM re-query: Thank you for adding the events. However the AE END DATE doesn't correspond to eDiary end date for MUSCLE ACHE (Day 14: AUG 21), FATIGUE (Day 14: 21 AUG). Please review and update as appropriate else clarify. ' (Site from DM). | (b) (4), (b) (6) | 08 Apr 2021 10:06:27 |

US3402284

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 17:25:19

[Did the participant experience any adverse events?](#)

| Audit | User | Time (GMT) |
|--|-------------------------------|----------------------|
| User closed query 'Per DM CLR: Per Safety Follow-up Diary Day 159, Experienced any new COVID-19 symptoms since last questionnaire or study contact?; and Have you contacted a healthcare provider since last questionnaire or study contact? = Yes, however, please note that there is no corresponding AE for this recorded data. Please reconcile and update to record the AE as applicable, otherwise provide clarification. ' (Site from DM). | (b) (4), (b) (6) | 08 Apr 2021 09:54:46 |
| User closed query 'Per DM CLR: Per Safety Follow Up Diary Day 166, '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 within this timeframe. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' (Site from DM). | (b) (4), (b) (6) | 08 Apr 2021 09:54:44 |
| Query 'Per DM CLR: Please note, Per Diary Dose 2 Record, the following symptoms persist beyond Day 7: JOINT ACHES (start date: Day 1; end date: Day 18); MUSCLE ACHES (Day 2-23). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification.' answered with 'ADDED AE'S ' (Site from DM). | Tammy Kohn (b) (4) (b) (4) | 07 Apr 2021 16:31:18 |
| Query 'Per DM CLR: Please note, Per Diary Dose 1 Record, the following symptoms persist beyond Day 7 : FATIGUE (start date: Day 1; end date: Day 14); JOINT ACHES (Day 1-12); MUSCLE ACHES (Day 1-14). Review if these should be recorded as Solicited Adverse Reactions per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification.' answered with 'ADDED AE'S ' (Site from DM). | Tammy Kohn (b) (4) (b) (4) | 07 Apr 2021 16:31:15 |

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Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 17:25:19

[Did the participant experience any adverse events?](#)

| Audit | User | Time (GMT) |
|---|-------------------------------|----------------------|
| Query 'Per DM CLR: Per Safety Follow-up Diary Day 159, Experienced any new COVID-19 symptoms since last questionnaire or study contact?; and Have you contacted a healthcare provider since last questionnaire or study contact? = Yes, however, please note that there is no corresponding AE for this recorded data. Please reconcile and update to record the AE as applicable, otherwise provide clarification. ' answered with 'SUBJECT WAS CONTACTED AND CAME IN FOR ILLNESS VISIT NEGATIVE COVID 19 RECORDED' (Site from DM). | Tammy Kohn (b) (4) (b) (4) | 07 Apr 2021 16:31:05 |
| Query 'Per DM CLR: Per Safety Follow Up Diary Day 166, '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 within this timeframe. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' answered with 'SUBJECT WAS CONTACTED AND CAME IN FOR ILLNESS VISIT NEGATIVE COVID 19 RECORDED' (Site from DM). | Tammy Kohn (b) (4) (b) (4) | 07 Apr 2021 16:31:02 |
| User opened query 'Per DM CLR: Per Safety Follow-up Diary Day 159, Experienced any new COVID-19 symptoms since last questionnaire or study contact?; and Have you contacted a healthcare provider since last questionnaire or study contact? = Yes, however, please note that there is no corresponding AE for this recorded data. Please reconcile and update to record the AE as applicable, otherwise provide clarification. ' (Site from DM). | (b) (4), (b) (6) (b) (4) | 03 Apr 2021 12:06:18 |

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Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 17:25:19

[Did the participant experience any adverse events?](#)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| User opened query 'Per DM CLR: Per Safety Follow Up Diary Day 166, '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 within this timeframe. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' (Site from DM). | (b) (4), (b) (6) | 26 Mar 2021 17:44:53 |
| User opened query 'Per DM CLR: Please note, Per Diary Dose 2 Record, the following symptoms persist beyond Day 7: JOINT ACHES (start date: Day 1; end date: Day 18); MUSCLE ACHES (Day 2-23). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification.' (Site from DM). | (b) (4), (b) (6) | 21 Mar 2021 11:08:07 |
| User opened query 'Per DM CLR: Please note, Per Diary Dose 1 Record, the following symptoms persist beyond Day 7 : FATIGUE (start date: Day 1; end date: Day 14); JOINT ACHES (Day 1-12); MUSCLE ACHES (Day 1-14). Review if these should be recorded as Solicited Adverse Reactions per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification.' (Site from DM). | (b) (4), (b) (6) | 21 Mar 2021 11:07:16 |
| User signature succeeded. | Frank Eder (b) (4) | 14 Mar 2021 14:43:49 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Nov 2020 20:33:28 |
| User entered 'Yes (Y)' reason for change: New Information | Jennifer Molstead (b) (4) | 24 Sep 2020 20:31:47 |
| User entered 'No (N)' | Traci Hull (b) (4) | 08 Aug 2020 20:43:05 |

US3402284

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:25:19

[AEID](#)

| Audit | User | Time (GMT) |
|---------------------------------------|--------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 14 Mar 2021 14:43:49 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 24 Nov 2020 15:30:10 |
| | | |
| Reviewed for Safety. | (b) (4), (b) (6) | 25 Sep 2020 15:16:41 |
| | | |
| User entered | System | 25 Sep 2020 15:16:36 |
| 'USA-US059-2020-mRNA-1273-P301000004' | | |
| User entered 'New' | (b) (4), (b) (6) | 25 Sep 2020 15:16:36 |
| | | |

US3402284

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:25:19

[Adverse event](#)

| Audit | User | Time (GMT) |
|---|---------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 14 Mar 2021 14:43:49 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 24 Nov 2020 15:30:10 |
| | | |
| User coded data point as SOC: Renal and urinary disorders, HLGT: Urolithiasis, HLT: Renal lithiasis, PT: Nephrolithiasis, LLT: Kidney stone - version MedDRA\\23.0. | Coder Import (b) (4) | 24 Sep 2020 20:39:44 |
| | (b) (4) | |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 24 Sep 2020 20:39:44 |
| | (b) (4) | |
| Data point term sent to Coder | System | 24 Sep 2020 20:38:18 |
| User entered 'Kidney Stone' | Jennifer Molstead (b) (4) | 24 Sep 2020 20:37:45 |
| | (b) (4) | |

US3402284

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:25:19

[Was this a medically-attended AE?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 14 Mar 2021 14:43:49 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 15:30:10 |
| User entered 'Yes (Y)' | Jennifer Molstead (b) (4) (b) (4) | 24 Sep 2020 20:37:45 |

US3402284

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:25:19

[Was this a Solicited Adverse Reaction?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 14 Mar 2021 14:43:49 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 15:30:10 |
| User entered 'No (N)' | Jennifer Molstead (b) (4) (b) (4) | 24 Sep 2020 20:37:45 |

US3402284

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:25:19

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 14 Mar 2021 14:43:49 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 15:30:10 |
| User entered 'No (N)' | Jennifer Molstead (b) (4) (b) (4) | 24 Sep 2020 20:37:45 |

US3402284

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:25:19

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 14 Mar 2021 14:43:49 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 15:30:10 |
| User entered '22 Sep 2020' | Jennifer Molstead (b) (4) (b) (4) | 24 Sep 2020 20:37:45 |

US3402284

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:25:19

Start time (00:00-23:59)

| Audit | User | Time (GMT) |
|--|--------------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 14 Mar 2021 14:43:49 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 15:30:10 |
| User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System). | System | 12 Oct 2020 13:02:44 |
| User entered empty; reason for change Data Entry Error | Tammy Kohn (b) (4) (b) (4) | 12 Oct 2020 13:02:44 |
| User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System). | System | 24 Sep 2020 20:37:45 |
| User entered '08:00' | Jennifer Molstead (b) (4) (b) (4) | 24 Sep 2020 20:37:45 |

US3402284

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:25:19

[AE start date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered empty. | System | 12 Oct 2020 13:02:44 |
| User entered '22 Sep 2020 08:00' | System | 24 Sep 2020 20:37:45 |

US3402284

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:25:19

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 14 Mar 2021 14:43:49 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 15:30:10 |
| User entered 'No (N)' | Jennifer Molstead (b) (4) (b) (4) | 24 Sep 2020 20:37:45 |

US3402284

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:25:19

If not Ongoing, end date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 14 Mar 2021 14:43:49 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 15:30:10 |
| User entered '23 Sep 2020' | Jennifer Molstead (b) (4) (b) (4) | 24 Sep 2020 20:37:45 |

US3402284

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:25:19

End time (00:00-23:59)

| Audit | User | Time (GMT) |
|--|--------------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 14 Mar 2021 14:43:49 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 15:30:10 |
| User closed query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System). | System | 12 Oct 2020 13:02:44 |
| User entered empty; reason for change Data Entry Error | Tammy Kohn (b) (4) (b) (4) | 12 Oct 2020 13:02:44 |
| User opened query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System). | System | 24 Sep 2020 20:37:45 |
| User entered '11:30' | Jennifer Molstead (b) (4) (b) (4) | 24 Sep 2020 20:37:45 |

US3402284

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:25:19

[AE End Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|--------|----------------------|
| User entered empty. | System | 12 Oct 2020 13:02:44 |
| User entered '23 Sep 2020 11:30' | System | 24 Sep 2020 20:37:45 |

US3402284

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:25:19

[Severity](#)

| Audit | User | Time (GMT) |
|--|--------------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 14 Mar 2021 14:43:49 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 15:30:10 |
| User entered 'Grade 3/Severe (Grade 3/Severe)' | Jennifer Molstead (b) (4) (b) (4) | 24 Sep 2020 20:37:45 |

US3402284

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:25:19

[Is the adverse event serious?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 14 Mar 2021 14:43:49 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 15:30:10 |
| User entered 'Yes (Y)' | Jennifer Molstead (b) (4) (b) (4) | 24 Sep 2020 20:37:45 |

US3402284

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:25:19

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 14 Mar 2021 14:43:49 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 15:30:10 |
| User entered '0' | Jennifer Molstead (b) (4) (b) (4) | 24 Sep 2020 20:37:45 |

US3402284

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:25:19

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 14 Mar 2021 14:43:49 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 15:30:10 |
| User entered '0' | Jennifer Molstead (b) (4) (b) (4) | 24 Sep 2020 20:37:45 |

US3402284

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:25:19

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 14 Mar 2021 14:43:49 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 15:30:10 |
| User entered 'I' | Jennifer Molstead (b) (4) (b) (4) | 24 Sep 2020 20:37:45 |

US3402284

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:25:19

Hospital Admission Date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 14 Mar 2021 14:43:49 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 24 Nov 2020 15:30:10 |
| | | |
| User entered '22 Sep 2020' | Jennifer Molstead (b) (4) | 24 Sep 2020 20:37:45 |
| | (b) (4) | |

US3402284

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:25:19

Hospital Discharge Date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 14 Mar 2021 14:43:49 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 15:30:10 |
| User entered '23 Sep 2020' | Jennifer Molstead (b) (4) (b) (4) | 24 Sep 2020 20:37:45 |

US3402284

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:25:19

[Admitted to ICU?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 14 Mar 2021 14:43:49 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 15:30:10 |
| User entered 'No (N)' | Jennifer Molstead (b) (4) (b) (4) | 24 Sep 2020 20:37:45 |

US3402284

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:25:19

[Number of Days in ICU](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 14 Mar 2021 14:43:49 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 15:30:10 |
| User entered empty. | Jennifer Molstead (b) (4) (b) (4) | 24 Sep 2020 20:37:45 |

US3402284

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:25:19

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 14 Mar 2021 14:43:49 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 15:30:10 |
| User entered '0' | Jennifer Molstead (b) (4) (b) (4) | 24 Sep 2020 20:37:45 |

US3402284

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:25:19

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 14 Mar 2021 14:43:49 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 15:30:10 |
| User entered '0' | Jennifer Molstead (b) (4) (b) (4) | 24 Sep 2020 20:37:45 |

US3402284

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:25:19

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 14 Mar 2021 14:43:49 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 15:30:10 |
| User entered '0' | Jennifer Molstead (b) (4) (b) (4) | 24 Sep 2020 20:37:45 |

US3402284

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:25:19

[Relationship to investigational product](#)

| Audit | User | Time (GMT) |
|--|--------------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 14 Mar 2021 14:43:49 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 15:30:10 |
| User entered 'Not Related (NOT RELATED)' | Jennifer Molstead (b) (4) (b) (4) | 24 Sep 2020 20:37:45 |

US3402284

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:25:19

[Relationship to Study Procedure](#)

| Audit | User | Time (GMT) |
|--|--------------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 14 Mar 2021 14:43:49 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 15:30:10 |
| User entered 'Not Related (NOT RELATED)' | Jennifer Molstead (b) (4) (b) (4) | 24 Sep 2020 20:37:45 |

US3402284

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:25:19

Action taken with investigational product

| Audit | User | Time (GMT) |
|---|--------------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 14 Mar 2021 14:43:49 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 15:30:10 |
| User closed query 'PV Query: As the last dose of mRNA-1273 or placebo was given on 10 Sep 2020, please update the action taken with study drug from none to not applicable.' (Site from Safety). | (b) (4), (b) (6) | 13 Oct 2020 13:01:18 |
| Query 'PV Query: As the last dose of mRNA-1273 or placebo was given on 10 Sep 2020, please update the action taken with study drug from none to not applicable.' answered with 'DATA UPDATED' (Site from Safety). | Tammy Kohn (b) (4) (b) (4) | 12 Oct 2020 13:05:01 |
| User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error | Tammy Kohn (b) (4) (b) (4) | 12 Oct 2020 13:04:55 |
| User opened query 'PV Query: As the last dose of mRNA-1273 or placebo was given on 10 Sep 2020, please update the action taken with study drug from none to not applicable.' (Site from Safety). | (b) (4), (b) (6) | 02 Oct 2020 17:42:59 |
| User entered 'None (NONE)' | Jennifer Molstead (b) (4) (b) (4) | 24 Sep 2020 20:37:45 |

US3402284

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:25:19

[None](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 14 Mar 2021 14:43:49 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 15:30:10 |
| User entered '0' | Jennifer Molstead (b) (4) (b) (4) | 24 Sep 2020 20:37:45 |

US3402284

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:25:19

[Concomitant Medication](#)

| Audit | User | Time (GMT) |
|---|---|--|
| User signature succeeded. | Frank Eder (b) (4) | 14 Mar 2021 14:43:49 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 15:30:10 |
| User closed query 'Per DM CLR: Please review Other Action Taken and please note that there are recorded medications indicated for this AE. However, ConMed is not listed as Other Action Taken. Please review and update Other Action Taken as appropriate. Otherwise, clarify.' (Site from DM). Query 'Per DM CLR: Please review Other Action Taken and please note that there are recorded medications indicated for this AE. However, ConMed is not listed as Other Action Taken. Please review and update Other Action Taken as appropriate. Otherwise, clarify.' answered with 'updated' (Site from DM). | (b) (4), (b) (6) | 03 Nov 2020 13:52:08 |
| User entered '1' reason for change: Per Query Resolution | Jennifer Molstead (b) (4) (b) (4) | 29 Oct 2020 21:45:44 |
| User opened query 'Per DM CLR: Please review Other Action Taken and please note that there are recorded medications indicated for this AE. However, ConMed is not listed as Other Action Taken. Please review and update Other Action Taken as appropriate. Otherwise, clarify.' (Site from DM). User entered '0' | Jennifer Molstead (b) (4) (b) (4), (b) (6) | 29 Oct 2020 21:45:33 28 Oct 2020 14:15:58 |
| | Jennifer Molstead (b) (4) (b) (4) | 24 Sep 2020 20:37:45 |

US3402284

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:25:19

[Concomitant Procedure](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 14 Mar 2021 14:43:49 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 15:30:10 |
| User entered 'I' | Jennifer Molstead (b) (4) (b) (4) | 24 Sep 2020 20:37:45 |

US3402284

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:25:19

[Outcome](#)

| Audit | User | Time (GMT) |
|---|--------------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 14 Mar 2021 14:43:49 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 15:30:10 |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' | Jennifer Molstead (b) (4) (b) (4) | 24 Sep 2020 20:37:45 |

US3402284

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:25:19

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 14 Mar 2021 14:43:49 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 15:30:10 |
| User entered empty. | Jennifer Molstead (b) (4) (b) (4) | 24 Sep 2020 20:37:45 |

US3402284

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:25:19

[Narrative](#)

| Audit | User | Time (GMT) |
|--|-------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 14 Mar 2021 14:43:49 |
| User closed query 'Per DM CLR: Narrative indicates that the subject also received Sodium Chloride 0.9% at a 100 mL/Hr rate. However, there is no corresponding ConMed record that match the information. Please update to record the corresponding ConMed as appropriate. Otherwise, clarify.' (Site from DM). | (b) (4) (b) (4), (b) (6) | 03 Dec 2020 11:43:15 |
| Query 'Per DM CLR: Narrative indicates that the subject also received Sodium Chloride 0.9% at a 100 mL/Hr rate. However, there is no corresponding ConMed record that match the information. Please update to record the corresponding ConMed as appropriate. Otherwise, clarify.' answered with 'MEDICATION HAS BEEN ADDED TO CONMED LOG' (Site from DM). | Tammy Kohn (b) (4) (b) (4) | 01 Dec 2020 17:26:31 |
| User opened query 'Per DM CLR: Narrative indicates that the subject also received Sodium Chloride 0.9% at a 100 mL/Hr rate. However, there is no corresponding ConMed record that match the information. Please update to record the corresponding ConMed as appropriate. Otherwise, clarify.' (Site from DM). | (b) (4), (b) (6) | 28 Nov 2020 17:13:11 |
| DataPoint Verified. | (b) (4), (b) (6) | 24 Nov 2020 17:16:18 |
| DataPoint Un-verified. | | 24 Nov 2020 15:30:19 |
| DataPoint Verified. | | 24 Nov 2020 15:30:10 |
| User closed query 'Per DM CLR: SAE Narrative indicates that the subject underwent CT Scan of Abdomen and Pelvis and it appears that the subject had a Complete Blood Count. However, there are not recorded Concomitant Procedures that match these information. Please update to record the procedures as appropriate. Otherwise, clarify.' (Site from DM). | | 02 Nov 2020 08:31:27 |

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:25:19

[Narrative](#)

| Audit | User | Time (GMT) |
|--|---------------------------|----------------------|
| Query 'Per DM CLR: SAE Narrative indicates that the subject underwent CT Scan of Abdomen and Pelvis and it appears that the subject had a Complete Blood Count. However, there are not recorded Concomitant Procedures that match these information. Please update to record the procedures as appropriate. Otherwise, clarify.' answered with 'Updated' (Site from DM). | Jennifer Molstead (b) (4) | 29 Oct 2020 21:45:43 |
| User opened query 'Per DM CLR: SAE Narrative indicates that the subject underwent CT Scan of Abdomen and Pelvis and it appears that the subject had a Complete Blood Count. However, there are not recorded Concomitant Procedures that match these information. Please update to record the procedures as appropriate. Otherwise, clarify.' (Site from DM). | (b) (4), (b) (6) | 28 Oct 2020 14:16:16 |
| 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).' (Site from Safety). | (b) (4), (b) (6) | 14 Oct 2020 14:03:24 |
| 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) | 14 Oct 2020 14:03:20 |
| User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety). | (b) (4), (b) (6) | 14 Oct 2020 14:03:18 |
| 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).' answered with 'UPDATED' (Site from Safety). | Jennifer Molstead (b) (4) | 13 Oct 2020 22:14:59 |

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:25:19

[Narrative](#)

| Audit | User | Time (GMT) |
|--|---------------------------|----------------------|
| 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). | Jennifer Molstead (b) (4) | 13 Oct 2020 22:14:53 |
| User entered 'SUBJECT HAD SEVERE PAIN THE MORNING OF 22SEP2020. HE WENT TO THE ER AND WAS ADMITTED FOR EMERGENCY LITHOTRIPSY. PROCEDURE WITH STENT PLACEMENT WAS PERFORMED. SUBJECT WAS KEPT OVER NIGHT AND DISCHARGED 23SEP2020 AT 11:30. SUBJECT HAD A WHITE BLOOD COUNT OF 15.1UL, NORMAL IS 10.3 UL, CT ABDOMEN AND PELVIS: LEFT OBSTRUCTIVE UROPATHY DUE TO 4.5MM DISTAL URETERAL STONE. SUBJECT WAS GIVEN CEFTRIAZONE 1G IV DAILY, HEPARIN 5,000 UNITS Q12H, KETOROLAC 30MG IV Q6H, TAMSULOSIN 0.4 MG PO DAILY. SUBJECT WAS ALSO GIVEN SODIUM CHLORIDE 0.9% 100ML/HR. COVID-19 TESTING WAS PERFORMED 22SEP2020 RESULT WAS NEGATIVE.' reason for change: Per Query Resolution | Jennifer Molstead (b) (4) | 13 Oct 2020 22:14:47 |
| User entered 'SUBJECT HAD SEVERE PAIN THE MORNING OF 22SEP2020. HE WENT TO THE ER AND WAS ADMITTED FOR EMERGENCY LITHOTRIPSY. PROCEDURE WITH STENT PLACEMENT WAS PERFORMED. SUBJECT WAS KEPT OVER NIGHT AND DISCHARGED 23SEP2020 AT 11:30. SUBJECT HAD A WHITE BLOOD COUNT OF 15.1UL, NORMAL IS 10.3 UL, CT ABDOMEN AND PELVIS: LEFT OBSTRUCTIVE UROPATHY DUE TO 4.5MM DISTAL URETERAL STONE. SUBJECT WAS GIVEN CEFTRIAZONE 1G IV DAILY, HEPARIN 5,000 UNITS Q12H, KETOROLAC 30MG IV Q6H, TAMSULOSIN 0.4 MG PO DAILY. SUBJECT WAS ALSO GIVEN SODIUM CHLORIDE 0.9% 100ML/HR. COVID-19 TESTING WAS PERFORMED RESULT WAS NEGATIVE.' reason for change: Per Query Resolution | Jennifer Molstead (b) (4) | 13 Oct 2020 22:14:16 |

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:25:19

[Narrative](#)

| Audit | User | Time (GMT) |
|--|---------------------------|------------------------------|
| Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'UPDATED' (Site from Safety). | Jennifer Molstead (b) (4) | (b) (4) 13 Oct 2020 22:13:21 |
| User entered 'SUBJECT HAD SEVERE PAIN THE MORNING OF 22SEP2020. HE WENT TO THE ER AND WAS ADMITTED FOR EMERGENCY LITHOTRIPSY. PROCEDURE WITH STENT PLACEMENT WAS PERFORMED. SUBJECT WAS KEPT OVER NIGHT AND DISCHARGED 23SEP2020 AT 11:30. SUBJECT HAD A WHITE BLOOD COUNT OF 15.1uL, NORMAL IS 10.3 uL, CT ABDOMEN AND PELVIS: LEFT OBSTRUCTIVE UROPATHY DUE TO 4.5MM DISTAL URETERAL STONE. SUBJECT WAS GIVEN CEFTRIAZONE 1g IV DAILY, HEPARIN 5,000 UNITS Q12H, KETOROLAC 30MG IV Q6H, TAMSULOSIN 0.4 MG PO DAILY. SUBJECT WAS ALSO GIVEN SODIUM CHLORIDE 0.9% 100ML/HR.' reason for change: Per Query Resolution | Jennifer Molstead (b) (4) | (b) (4) 13 Oct 2020 22:13:02 |
| 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).' (Site from Safety). | (b) (4), (b) (6) | 02 Oct 2020 17:42:36 |
| 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) | 02 Oct 2020 17:42:26 |
| User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety). | (b) (4), (b) (6) | 02 Oct 2020 17:42:01 |

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:25:19

[Narrative](#)

| Audit | User | Time (GMT) |
|---|---------------------------|----------------------|
| User entered 'Subject had severe pain the morning of 22Sep2020. He went to the ER and was admitted for emergency lithotripsy. Procedure was performed subject was kept over night and discharged 23Sep2020 at 11:30. Awaiting medical records for update of medications given.' | Jennifer Molstead (b) (4) | 24 Sep 2020 20:37:45 |

US3402284

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:25:19

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 24 Sep 2020 20:37:45 |

US3402284

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:25:19

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 24 Sep 2020 20:37:45 |

US3402284

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:25:19

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '0' | System | 24 Sep 2020 20:37:45 |

US3402284

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:25:19

[AEID](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:37:07 |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:25:19

[Adverse event](#)

| Audit | User | Time (GMT) |
|---|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:37:07 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 17:24:14 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Asthenic conditions, PT: Fatigue, LLT: Fatigue - version MedDRA\\23.0. | (b) (4) | |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 07 Apr 2021 16:34:47 |
| Data point term sent to Coder | (b) (4) | |
| User entered 'FATIGUE' | System | 07 Apr 2021 16:33:34 |
| | Tammy Kohn (b) (4) | 07 Apr 2021 16:32:31 |
| | (b) (4) | |

US3402284

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:25:19

[Was this a medically-attended AE?](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:37:07 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 17:24:16 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| User entered 'No (N)' | (b) (4) Tammy Kohn (b) (4) (b) (4) | 07 Apr 2021 16:32:31 |

US3402284

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:25:19

[Was this a Solicited Adverse Reaction?](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:37:07 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 17:24:18 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| User entered 'Yes (Y)' | (b) (4) Tammy Kohn (b) (4) (b) (4) | 07 Apr 2021 16:32:31 |

US3402284

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:25:19

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:37:07 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 17:24:20 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| User entered 'No (N)' | (b) (4) Tammy Kohn (b) (4) (b) (4) | 07 Apr 2021 16:32:31 |

US3402284

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:37:07 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 17:24:22 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| User entered '8 Aug 2020' | (b) (4) Tammy Kohn (b) (4) (b) (4) | 07 Apr 2021 16:32:31 |

US3402284

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:25:19

[Start time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:37:07 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 17:24:23 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| User closed query 'Data is required. Please provide.' (Site from System). | (b) (4) | 07 Apr 2021 16:32:47 |
| User entered '06:00' reason for change: Data Entry Error | Tammy Kohn (b) (4) | 07 Apr 2021 16:32:47 |
| User opened query 'Data is required. Please provide.' (Site from System). | (b) (4) | 07 Apr 2021 16:32:31 |
| User entered empty. | System | 07 Apr 2021 16:32:31 |
| | Tammy Kohn (b) (4) | 07 Apr 2021 16:32:31 |
| | (b) (4) | |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:25:19

[AE start date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:37:07 |
| User entered '8 Aug 2020 06:00' | System | 07 Apr 2021 16:32:47 |
| User entered empty. | System | 07 Apr 2021 16:32:31 |

US3402284

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:25:19

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:37:07 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 17:24:25 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| User entered 'No (N)' | (b) (4) Tammy Kohn (b) (4) (b) (4) | 07 Apr 2021 16:32:31 |

US3402284

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:25:19

If not Ongoing, end date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:37:07 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 17:24:27 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| User entered '21 Aug 2020' reason for change: Data Entry Error | (b) (4) | 08 Apr 2021 15:37:07 |
| User entered '15 Aug 2020' | Tammy Kohn (b) (4) | 07 Apr 2021 16:32:31 |
| | (b) (4) | |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:25:19

[End time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:37:07 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 17:24:29 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| User closed query 'Data is required. Please provide.' (Site from System). | (b) (4) | 07 Apr 2021 16:32:47 |
| User entered '15:00' reason for change: Data Entry Error | Tammy Kohn (b) (4) | 07 Apr 2021 16:32:47 |
| User opened query 'Data is required. Please provide.' (Site from System). | (b) (4) | 07 Apr 2021 16:32:31 |
| User entered empty. | System | 07 Apr 2021 16:32:31 |
| | Tammy Kohn (b) (4) | 07 Apr 2021 16:32:31 |
| | (b) (4) | |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:25:19

[AE End Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:37:07 |
| User entered '21 Aug 2020 15:00' | System | 08 Apr 2021 15:37:07 |
| User entered '15 Aug 2020 15:00' | System | 07 Apr 2021 16:32:47 |
| User entered empty. | System | 07 Apr 2021 16:32:31 |

US3402284

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:25:19

[Severity](#)

| Audit | User | Time (GMT) |
|--|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:37:07 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 17:24:31 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| User entered 'Grade 1/Mild (Grade 1/Mild)' | (b) (4) Tammy Kohn (b) (4) (b) (4) | 07 Apr 2021 16:32:31 |

US3402284

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:25:19

[Is the adverse event serious?](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:37:07 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 17:24:33 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| User entered 'No (N)' | (b) (4) Tammy Kohn (b) (4) (b) (4) | 07 Apr 2021 16:32:31 |

US3402284

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:25:19

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:37:07 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 17:25:14 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| User entered '0' | (b) (4) Tammy Kohn (b) (4) (b) (4) | 07 Apr 2021 16:32:31 |

US3402284

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:25:19

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:37:07 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 17:25:15 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| User entered '0' | (b) (4) Tammy Kohn (b) (4) (b) (4) | 07 Apr 2021 16:32:31 |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:25:19

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:37:07 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 17:25:17 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| User entered '0' | (b) (4) Tammy Kohn (b) (4) (b) (4) | 07 Apr 2021 16:32:31 |

US3402284

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:25:19

Hospital Admission Date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:37:07 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 17:25:19 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| User entered empty. | (b) (4) Tammy Kohn (b) (4) (b) (4) | 07 Apr 2021 16:32:31 |

US3402284

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:25:19

Hospital Discharge Date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:37:07 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 17:25:20 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| User entered empty. | (b) (4) Tammy Kohn (b) (4) (b) (4) | 07 Apr 2021 16:32:31 |

US3402284

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:25:19

[Admitted to ICU?](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:37:07 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 17:25:23 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| User entered empty. | (b) (4) Tammy Kohn (b) (4) (b) (4) | 07 Apr 2021 16:32:31 |

US3402284

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:25:19

[Number of Days in ICU](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:37:07 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 17:25:24 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| User entered empty. | (b) (4) Tammy Kohn (b) (4) (b) (4) | 07 Apr 2021 16:32:31 |

US3402284

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:25:19

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:37:07 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 17:25:26 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| User entered '0' | (b) (4) Tammy Kohn (b) (4) (b) (4) | 07 Apr 2021 16:32:31 |

US3402284

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:25:19

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:37:07 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 17:25:28 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| User entered '0' | (b) (4) Tammy Kohn (b) (4) (b) (4) | 07 Apr 2021 16:32:31 |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:25:19

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:37:07 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 17:25:30 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| User entered '0' | (b) (4) Tammy Kohn (b) (4) (b) (4) | 07 Apr 2021 16:32:31 |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:25:19

[Relationship to investigational product](#)

| Audit | User | Time (GMT) |
|----------------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:37:07 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 17:25:32 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| User entered 'Related (RELATED)' | (b) (4) Tammy Kohn (b) (4) (b) (4) | 07 Apr 2021 16:32:31 |

US3402284

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:25:19

[Relationship to Study Procedure](#)

| Audit | User | Time (GMT) |
|----------------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:37:07 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 17:25:34 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| User entered 'Related (RELATED)' | (b) (4) Tammy Kohn (b) (4) (b) (4) | 07 Apr 2021 16:32:31 |

US3402284

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:25:19

[Action taken with investigational product](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:37:07 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 17:25:36 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| User entered 'None (NONE)' | (b) (4) Tammy Kohn (b) (4) (b) (4) | 07 Apr 2021 16:32:31 |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:25:19

[None](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:37:07 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 17:25:39 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| User entered 'l' | (b) (4) Tammy Kohn (b) (4) (b) (4) | 07 Apr 2021 16:32:31 |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:25:19

[Concomitant Medication](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:37:07 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 17:25:41 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| User entered '0' | (b) (4) Tammy Kohn (b) (4) (b) (4) | 07 Apr 2021 16:32:31 |

US3402284

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:25:19

[Concomitant Procedure](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:37:07 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 17:25:44 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| User entered '0' | (b) (4) Tammy Kohn (b) (4) (b) (4) | 07 Apr 2021 16:32:31 |

US3402284

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:25:19

[Outcome](#)

| Audit | User | Time (GMT) |
|---|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:37:07 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 17:25:46 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' | (b) (4) Tammy Kohn (b) (4) (b) (4) | 07 Apr 2021 16:32:31 |

US3402284

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:25:19

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:37:07 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 17:25:48 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| User entered empty. | (b) (4) Tammy Kohn (b) (4) (b) (4) | 07 Apr 2021 16:32:31 |

US3402284

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:25:19

[Narrative](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:37:07 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 17:25:50 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| User entered empty. | (b) (4) Tammy Kohn (b) (4) (b) (4) | 07 Apr 2021 16:32:31 |

US3402284

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:25:19

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:37:07 |
| User entered '0' | System | 07 Apr 2021 16:32:31 |

US3402284

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:25:19

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:37:07 |
| User entered '0' | System | 07 Apr 2021 16:32:31 |

US3402284

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:25:19

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:37:07 |

US3402284

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:25:19

[AEID](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:37:17 |

US3402284

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:25:19

[Adverse event](#)

| Audit | User | Time (GMT) |
|--|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:37:17 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 17:27:14 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related signs and symptoms, PT: Arthralgia, LLT: Joint ache - version MedDRA\\23.0. | (b) (4) Coder Import (b) (4) (b) (4) | 07 Apr 2021 16:35:33 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 07 Apr 2021 16:35:33 |
| Data point term sent to Coder | System | 07 Apr 2021 16:34:36 |
| User entered 'JOINT ACHES' | Tammy Kohn (b) (4) (b) (4) | 07 Apr 2021 16:34:02 |

US3402284

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:25:19

[Was this a medically-attended AE?](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:37:17 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 17:27:17 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| User entered 'No (N)' | (b) (4) Tammy Kohn (b) (4) (b) (4) | 07 Apr 2021 16:34:02 |

US3402284

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:25:19

[Was this a Solicited Adverse Reaction?](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:37:17 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 17:27:19 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| User entered 'Yes (Y)' | (b) (4) Tammy Kohn (b) (4) (b) (4) | 07 Apr 2021 16:34:02 |

US3402284

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:25:19

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:37:17 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 17:27:21 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| User entered 'No (N)' | (b) (4) Tammy Kohn (b) (4) (b) (4) | 07 Apr 2021 16:34:02 |

US3402284

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:37:17 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 17:27:23 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| User entered '8 Aug 2020' | (b) (4) Tammy Kohn (b) (4) (b) (4) | 07 Apr 2021 16:34:02 |

US3402284

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:25:19

[Start time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:37:17 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 17:27:25 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| User entered '06:00' | (b) (4) Tammy Kohn (b) (4) (b) (4) | 07 Apr 2021 16:34:02 |

US3402284

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:25:19

[AE start date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:37:17 |
| User entered '8 Aug 2020 06:00' | System | 07 Apr 2021 16:34:02 |

US3402284

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:25:19

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:37:17 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 17:27:26 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| User entered 'No (N)' | (b) (4) Tammy Kohn (b) (4) (b) (4) | 07 Apr 2021 16:34:02 |

US3402284

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:25:19

If not Ongoing, end date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:37:17 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 17:27:29 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| User entered '19 Aug 2020' | (b) (4) Tammy Kohn (b) (4) (b) (4) | 07 Apr 2021 16:34:02 |

US3402284

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:25:19

[End time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:37:17 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 17:27:32 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| User closed query 'Data is required. Please provide.' (Site from System). | (b) (4) | 07 Apr 2021 16:34:13 |
| User entered '14:00' reason for change: Data Entry Error | Tammy Kohn (b) (4) | 07 Apr 2021 16:34:13 |
| User opened query 'Data is required. Please provide.' (Site from System). | (b) (4) | 07 Apr 2021 16:34:02 |
| User entered empty. | System | 07 Apr 2021 16:34:02 |
| | Tammy Kohn (b) (4) | 07 Apr 2021 16:34:02 |
| | (b) (4) | |

US3402284

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:25:19

[AE End Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:37:17 |
| User entered '19 Aug 2020 14:00' | System | 07 Apr 2021 16:34:13 |
| User entered empty. | System | 07 Apr 2021 16:34:02 |

US3402284

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:25:19

[Severity](#)

| Audit | User | Time (GMT) |
|--|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:37:17 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 17:27:34 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| User entered 'Grade 1/Mild (Grade 1/Mild)' | (b) (4) Tammy Kohn (b) (4) (b) (4) | 07 Apr 2021 16:34:02 |

US3402284

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:25:19

[Is the adverse event serious?](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:37:17 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 17:27:35 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| User entered 'No (N)' | (b) (4) Tammy Kohn (b) (4) (b) (4) | 07 Apr 2021 16:34:02 |

US3402284

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:25:19

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:37:17 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 17:27:38 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| User entered '0' | (b) (4) Tammy Kohn (b) (4) (b) (4) | 07 Apr 2021 16:34:02 |

US3402284

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:25:19

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:37:17 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 17:27:40 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| User entered '0' | (b) (4) Tammy Kohn (b) (4) (b) (4) | 07 Apr 2021 16:34:02 |

US3402284

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:25:19

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:37:17 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 17:27:43 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| User entered '0' | (b) (4) Tammy Kohn (b) (4) (b) (4) | 07 Apr 2021 16:34:02 |

US3402284

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:25:19

Hospital Admission Date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:37:17 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 17:27:45 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| User entered empty. | (b) (4) Tammy Kohn (b) (4) (b) (4) | 07 Apr 2021 16:34:02 |

US3402284

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:25:19

[Hospital Discharge Date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:37:17 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 17:27:46 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| User entered empty. | (b) (4) Tammy Kohn (b) (4) (b) (4) | 07 Apr 2021 16:34:02 |

US3402284

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:25:19

[Admitted to ICU?](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:37:17 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 17:27:49 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| User entered empty. | (b) (4) Tammy Kohn (b) (4) (b) (4) | 07 Apr 2021 16:34:02 |

US3402284

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:25:19

[Number of Days in ICU](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:37:17 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 17:27:51 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| User entered empty. | (b) (4) Tammy Kohn (b) (4) (b) (4) | 07 Apr 2021 16:34:02 |

US3402284

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:25:19

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:37:17 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 17:27:52 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| User entered '0' | (b) (4) Tammy Kohn (b) (4) (b) (4) | 07 Apr 2021 16:34:02 |

US3402284

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:25:19

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:37:17 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 17:27:56 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| User entered '0' | (b) (4) Tammy Kohn (b) (4) (b) (4) | 07 Apr 2021 16:34:02 |

US3402284

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:25:19

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:37:17 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 17:27:59 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| User entered '0' | (b) (4) Tammy Kohn (b) (4) (b) (4) | 07 Apr 2021 16:34:02 |

US3402284

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:25:19

[Relationship to investigational product](#)

| Audit | User | Time (GMT) |
|----------------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:37:17 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 17:28:01 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| User entered 'Related (RELATED)' | (b) (4) Tammy Kohn (b) (4) (b) (4) | 07 Apr 2021 16:34:02 |

US3402284

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:25:19

[Relationship to Study Procedure](#)

| Audit | User | Time (GMT) |
|----------------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:37:17 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 17:28:03 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| User entered 'Related (RELATED)' | (b) (4) Tammy Kohn (b) (4) (b) (4) | 07 Apr 2021 16:34:02 |

US3402284

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:25:19

[Action taken with investigational product](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:37:17 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 17:28:05 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| User entered 'None (NONE)' | (b) (4) Tammy Kohn (b) (4) (b) (4) | 07 Apr 2021 16:34:02 |

US3402284

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:25:19

[None](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:37:17 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 17:28:07 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| User entered 'l' | (b) (4) Tammy Kohn (b) (4) (b) (4) | 07 Apr 2021 16:34:02 |

US3402284

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:25:19

[Concomitant Medication](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:37:17 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 17:28:09 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| User entered '0' | (b) (4) Tammy Kohn (b) (4) (b) (4) | 07 Apr 2021 16:34:02 |

US3402284

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:25:19

[Concomitant Procedure](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:37:17 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 17:28:11 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| User entered '0' | (b) (4) Tammy Kohn (b) (4) (b) (4) | 07 Apr 2021 16:34:02 |

US3402284

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:25:19

[Outcome](#)

| Audit | User | Time (GMT) |
|---|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:37:17 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 17:28:13 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' | (b) (4) Tammy Kohn (b) (4) (b) (4) | 07 Apr 2021 16:34:02 |

US3402284

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:25:19

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:37:17 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 17:28:15 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| User entered empty. | (b) (4) Tammy Kohn (b) (4) (b) (4) | 07 Apr 2021 16:34:02 |

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:25:19

[Narrative](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:37:17 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 17:28:17 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| User entered empty. | (b) (4) Tammy Kohn (b) (4) (b) (4) | 07 Apr 2021 16:34:02 |

US3402284

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:25:19

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:37:17 |
| User entered '0' | System | 07 Apr 2021 16:34:02 |

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:25:19

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:37:17 |
| User entered '0' | System | 07 Apr 2021 16:34:02 |

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:25:19

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:37:17 |

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:25:19

[AEID](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:37:23 |

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:25:19

[Adverse event](#)

| Audit | User | Time (GMT) |
|---|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:37:23 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 17:29:32 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Muscle disorders, HLT: Muscle pains, PT: Myalgia, LLT: Muscle ache - version MedDRA\\23.0. | (b) (4) | |
| | Coder Import (b) (4) | 07 Apr 2021 16:36:47 |
| | (b) (4) | |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 07 Apr 2021 16:36:47 |
| | (b) (4) | |
| Data point term sent to Coder | System | 07 Apr 2021 16:35:36 |
| User entered 'MUSCLE ACHES' | Tammy Kohn (b) (4) | 07 Apr 2021 16:35:24 |
| | (b) (4) | |

US3402284

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:25:19

[Was this a medically-attended AE?](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:37:23 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 17:29:34 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| User entered 'No (N)' | (b) (4) Tammy Kohn (b) (4) (b) (4) | 07 Apr 2021 16:35:24 |

US3402284

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:25:19

[Was this a Solicited Adverse Reaction?](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:37:23 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 17:29:36 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| User entered 'Yes (Y)' | (b) (4) Tammy Kohn (b) (4) (b) (4) | 07 Apr 2021 16:35:24 |

US3402284

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:25:19

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:37:23 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 17:29:37 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| User entered 'No (N)' | (b) (4) Tammy Kohn (b) (4) (b) (4) | 07 Apr 2021 16:35:24 |

US3402284

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:37:23 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 17:29:39 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| User entered '8 Aug 2020' | (b) (4) Tammy Kohn (b) (4) (b) (4) | 07 Apr 2021 16:35:24 |

US3402284

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:25:19

[Start time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:37:23 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 17:29:41 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| User entered '06:00' | (b) (4) Tammy Kohn (b) (4) (b) (4) | 07 Apr 2021 16:35:24 |

US3402284

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:25:19

[AE start date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:37:23 |
| User entered '8 Aug 2020 06:00' | System | 07 Apr 2021 16:35:24 |

US3402284

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:25:19

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:37:23 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 17:29:43 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| User entered 'No (N)' | (b) (4) Tammy Kohn (b) (4) (b) (4) | 07 Apr 2021 16:35:24 |

US3402284

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:25:19

If not Ongoing, end date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:37:23 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 17:29:45 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| User entered '21 Aug 2020' | (b) (4) Tammy Kohn (b) (4) (b) (4) | 07 Apr 2021 16:35:24 |

US3402284

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:25:19

[End time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:37:23 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 17:29:48 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| User closed query 'Data is required. Please provide.' (Site from System). | (b) (4) | 07 Apr 2021 16:35:38 |
| User entered '16:30' reason for change: Data Entry Error | Tammy Kohn (b) (4) | 07 Apr 2021 16:35:38 |
| User opened query 'Data is required. Please provide.' (Site from System). | (b) (4) | 07 Apr 2021 16:35:24 |
| User entered empty. | System | 07 Apr 2021 16:35:24 |
| | Tammy Kohn (b) (4) | 07 Apr 2021 16:35:24 |
| | (b) (4) | |

US3402284

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:25:19

[AE End Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:37:23 |
| User entered '21 Aug 2020 16:30' | System | 07 Apr 2021 16:35:38 |
| User entered empty. | System | 07 Apr 2021 16:35:24 |

US3402284

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:25:19

[Severity](#)

| Audit | User | Time (GMT) |
|--|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:37:23 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 17:29:49 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| User entered 'Grade 1/Mild (Grade 1/Mild)' | (b) (4) Tammy Kohn (b) (4) (b) (4) | 07 Apr 2021 16:35:24 |

US3402284

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:25:19

[Is the adverse event serious?](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:37:23 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 17:29:51 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| User entered 'No (N)' | (b) (4) Tammy Kohn (b) (4) (b) (4) | 07 Apr 2021 16:35:24 |

US3402284

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:25:19

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:37:23 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 17:29:55 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| User entered '0' | (b) (4) Tammy Kohn (b) (4) (b) (4) | 07 Apr 2021 16:35:24 |

US3402284

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:25:19

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:37:23 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 17:29:57 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| User entered '0' | (b) (4) Tammy Kohn (b) (4) (b) (4) | 07 Apr 2021 16:35:24 |

US3402284

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:25:19

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:37:23 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 17:29:59 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| User entered '0' | (b) (4) Tammy Kohn (b) (4) (b) (4) | 07 Apr 2021 16:35:24 |

US3402284

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:25:19

[Hospital Admission Date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:37:23 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 17:30:01 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| User entered empty. | (b) (4) Tammy Kohn (b) (4) (b) (4) | 07 Apr 2021 16:35:24 |

US3402284

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:25:19

[Hospital Discharge Date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:37:23 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 17:30:03 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| User entered empty. | (b) (4) Tammy Kohn (b) (4) (b) (4) | 07 Apr 2021 16:35:24 |

US3402284

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:25:19

[Admitted to ICU?](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:37:23 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 17:30:06 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| User entered empty. | (b) (4) Tammy Kohn (b) (4) (b) (4) | 07 Apr 2021 16:35:24 |

US3402284

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:25:19

[Number of Days in ICU](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:37:23 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 17:30:13 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| User entered empty. | (b) (4) Tammy Kohn (b) (4) | 07 Apr 2021 16:35:24 |

US3402284

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:25:19

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:37:23 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 17:30:20 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| User entered '0' | (b) (4) Tammy Kohn (b) (4) (b) (4) | 07 Apr 2021 16:35:24 |

US3402284

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:25:19

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:37:23 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 17:30:25 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| User entered '0' | (b) (4) Tammy Kohn (b) (4) (b) (4) | 07 Apr 2021 16:35:24 |

US3402284

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:25:19

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:37:23 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 17:30:28 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| User entered '0' | (b) (4) Tammy Kohn (b) (4) (b) (4) | 07 Apr 2021 16:35:24 |

US3402284

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:25:19

[Relationship to investigational product](#)

| Audit | User | Time (GMT) |
|----------------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:37:23 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 17:30:30 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| User entered 'Related (RELATED)' | (b) (4) Tammy Kohn (b) (4) (b) (4) | 07 Apr 2021 16:35:24 |

US3402284

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:25:19

[Relationship to Study Procedure](#)

| Audit | User | Time (GMT) |
|----------------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:37:23 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 17:30:32 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| User entered 'Related (RELATED)' | (b) (4) Tammy Kohn (b) (4) (b) (4) | 07 Apr 2021 16:35:24 |

US3402284

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:25:19

[Action taken with investigational product](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:37:23 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 17:30:34 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| User entered 'None (NONE)' | (b) (4) Tammy Kohn (b) (4) (b) (4) | 07 Apr 2021 16:35:24 |

US3402284

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:25:19

[None](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:37:23 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 17:30:37 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| User entered 'l' | (b) (4) Tammy Kohn (b) (4) (b) (4) | 07 Apr 2021 16:35:24 |

US3402284

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:25:19

[Concomitant Medication](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:37:23 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 17:30:39 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| User entered '0' | (b) (4) Tammy Kohn (b) (4) (b) (4) | 07 Apr 2021 16:35:24 |

US3402284

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:25:19

[Concomitant Procedure](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:37:23 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 17:30:41 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| User entered '0' | (b) (4) Tammy Kohn (b) (4) (b) (4) | 07 Apr 2021 16:35:24 |

US3402284

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:25:19

[Outcome](#)

| Audit | User | Time (GMT) |
|---|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:37:23 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 17:30:43 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' | (b) (4) Tammy Kohn (b) (4) (b) (4) | 07 Apr 2021 16:35:24 |

US3402284

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:25:19

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:37:23 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 17:30:45 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| User entered empty. | (b) (4) Tammy Kohn (b) (4) (b) (4) | 07 Apr 2021 16:35:24 |

US3402284

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:25:19

[Narrative](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:37:23 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 17:30:47 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| User entered empty. | (b) (4) Tammy Kohn (b) (4) (b) (4) | 07 Apr 2021 16:35:24 |

US3402284

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:25:19

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:37:23 |
| User entered '0' | System | 07 Apr 2021 16:35:24 |

US3402284

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:25:19

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:37:23 |
| User entered '0' | System | 07 Apr 2021 16:35:24 |

US3402284

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:25:19

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:37:23 |
| | | |

US3402284

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:25:19

[AEID](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:37:27 |

US3402284

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:25:19

[Adverse event](#)

| Audit | User | Time (GMT) |
|--|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:37:27 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 17:31:03 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related signs and symptoms, PT: Arthralgia, LLT: Joint ache - version MedDRA\\23.0. | (b) (4) Coder Import (b) (4) (b) (4) | 07 Apr 2021 16:38:47 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 07 Apr 2021 16:38:47 |
| Data point term sent to Coder | System | 07 Apr 2021 16:37:50 |
| User entered 'JOINT ACHES' | Tammy Kohn (b) (4) (b) (4) | 07 Apr 2021 16:36:45 |

US3402284

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:25:19

[Was this a medically-attended AE?](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:37:27 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 17:31:05 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| User entered 'No (N)' | (b) (4) Tammy Kohn (b) (4) (b) (4) | 07 Apr 2021 16:36:45 |

US3402284

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:25:19

[Was this a Solicited Adverse Reaction?](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:37:27 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 17:31:07 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| User entered 'Yes (Y)' | (b) (4) Tammy Kohn (b) (4) (b) (4) | 07 Apr 2021 16:36:45 |

US3402284

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:25:19

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:37:27 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 17:31:11 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| User entered 'No (N)' | (b) (4) Tammy Kohn (b) (4) (b) (4) | 07 Apr 2021 16:36:45 |

US3402284

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:37:27 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 17:31:14 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| User entered '10 Sep 2020' | (b) (4) Tammy Kohn (b) (4) (b) (4) | 07 Apr 2021 16:36:45 |

US3402284

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:25:19

[Start time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:37:27 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 17:31:20 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| User entered '06:35' | (b) (4) Tammy Kohn (b) (4) (b) (4) | 07 Apr 2021 16:36:45 |

US3402284

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:25:19

[AE start date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:37:27 |
| User entered '10 Sep 2020 06:35' | System | 07 Apr 2021 16:36:45 |

US3402284

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:25:19

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:37:27 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 17:31:22 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| User entered 'No (N)' | (b) (4) Tammy Kohn (b) (4) (b) (4) | 07 Apr 2021 16:36:45 |

US3402284

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:25:19

If not Ongoing, end date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:37:27 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 17:31:24 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| User closed query 'End date is prior to Start date. Please correct.' (Site from System). | (b) (4) | 07 Apr 2021 16:37:29 |
| User entered '27 Sep 2020' reason for change: Data Entry Error | System | 07 Apr 2021 16:37:29 |
| User opened query 'End date is prior to Start date. Please correct.' (Site from System). | Tammy Kohn (b) (4) | 07 Apr 2021 16:36:45 |
| User entered '27 Aug 2020' | (b) (4) | 07 Apr 2021 16:36:45 |

US3402284

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:25:19

End time (00:00-23:59)

| Audit | User | Time (GMT) |
|---|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:37:27 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 17:31:26 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| User closed query 'End time is prior or equal to Start time. Please correct.' (Site from System). | (b) (4) | 07 Apr 2021 16:37:29 |
| User entered '18:30' reason for change: Data Entry Error | Tammy Kohn (b) (4) | 07 Apr 2021 16:37:29 |
| User opened query 'End time is prior or equal to Start time. Please correct.' (Site from System). | (b) (4) | 07 Apr 2021 16:36:45 |
| User entered '18:00' | Tammy Kohn (b) (4) | 07 Apr 2021 16:36:45 |
| | (b) (4) | |

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:25:19

[AE End Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:37:27 |
| User entered '27 Sep 2020 18:30' | System | 07 Apr 2021 16:37:29 |
| User entered '27 Aug 2020 18:00' | System | 07 Apr 2021 16:36:45 |

US3402284

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:25:19

[Severity](#)

| Audit | User | Time (GMT) |
|--|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:37:27 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 17:31:27 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| User entered 'Grade 1/Mild (Grade 1/Mild)' | (b) (4) Tammy Kohn (b) (4) (b) (4) | 07 Apr 2021 16:36:45 |

US3402284

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:25:19

[Is the adverse event serious?](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:37:27 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 17:31:29 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| User entered 'No (N)' | (b) (4) Tammy Kohn (b) (4) (b) (4) | 07 Apr 2021 16:36:45 |

US3402284

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:25:19

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:37:27 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 17:31:38 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| User entered '0' | (b) (4) Tammy Kohn (b) (4) (b) (4) | 07 Apr 2021 16:36:45 |

US3402284

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:25:19

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:37:27 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 17:31:51 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| User entered '0' | (b) (4) Tammy Kohn (b) (4) (b) (4) | 07 Apr 2021 16:36:45 |

US3402284

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:25:19

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:37:27 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 17:31:53 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| User entered '0' | (b) (4) Tammy Kohn (b) (4) (b) (4) | 07 Apr 2021 16:36:45 |

US3402284

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:25:19

[Hospital Admission Date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:37:27 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 17:32:07 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| User entered empty. | (b) (4) Tammy Kohn (b) (4) (b) (4) | 07 Apr 2021 16:36:45 |

US3402284

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:25:19

Hospital Discharge Date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:37:27 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 17:32:09 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| User entered empty. | (b) (4) Tammy Kohn (b) (4) (b) (4) | 07 Apr 2021 16:36:45 |

US3402284

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:25:19

[Admitted to ICU?](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:37:27 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 17:32:10 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| User entered empty. | (b) (4) Tammy Kohn (b) (4) (b) (4) | 07 Apr 2021 16:36:45 |

US3402284

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:25:19

[Number of Days in ICU](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:37:27 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 17:32:12 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| User entered empty. | (b) (4) Tammy Kohn (b) (4) (b) (4) | 07 Apr 2021 16:36:45 |

US3402284

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:25:19

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:37:27 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 17:32:13 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| User entered '0' | (b) (4) Tammy Kohn (b) (4) (b) (4) | 07 Apr 2021 16:36:45 |

US3402284

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:25:19

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:37:27 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 17:32:15 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| User entered '0' | (b) (4) Tammy Kohn (b) (4) (b) (4) | 07 Apr 2021 16:36:45 |

US3402284

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:25:19

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:37:27 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 17:32:17 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| User entered '0' | (b) (4) Tammy Kohn (b) (4) (b) (4) | 07 Apr 2021 16:36:45 |

US3402284

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:25:19

[Relationship to investigational product](#)

| Audit | User | Time (GMT) |
|----------------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:37:27 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 17:32:19 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| User entered 'Related (RELATED)' | (b) (4) Tammy Kohn (b) (4) (b) (4) | 07 Apr 2021 16:36:45 |

US3402284

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:25:19

[Relationship to Study Procedure](#)

| Audit | User | Time (GMT) |
|----------------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:37:27 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 17:32:21 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| User entered 'Related (RELATED)' | (b) (4) Tammy Kohn (b) (4) (b) (4) | 07 Apr 2021 16:36:45 |

US3402284

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:25:19

[Action taken with investigational product](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:37:27 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 17:32:24 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| User entered 'None (NONE)' | (b) (4) Tammy Kohn (b) (4) (b) (4) | 07 Apr 2021 16:36:45 |

US3402284

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:25:19

[None](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:37:27 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 17:32:25 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| User entered 'l' | (b) (4) Tammy Kohn (b) (4) (b) (4) | 07 Apr 2021 16:36:45 |

US3402284

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:25:19

[Concomitant Medication](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:37:27 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 17:32:27 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| User entered '0' | (b) (4) Tammy Kohn (b) (4) (b) (4) | 07 Apr 2021 16:36:45 |

US3402284

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:25:19

[Concomitant Procedure](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:37:27 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 17:32:29 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| User entered '0' | (b) (4) Tammy Kohn (b) (4) (b) (4) | 07 Apr 2021 16:36:45 |

US3402284

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:25:19

[Outcome](#)

| Audit | User | Time (GMT) |
|---|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:37:27 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 17:32:30 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' | (b) (4) Tammy Kohn (b) (4) (b) (4) | 07 Apr 2021 16:36:45 |

US3402284

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:25:19

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:37:27 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 17:32:32 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| User entered empty. | (b) (4) Tammy Kohn (b) (4) (b) (4) | 07 Apr 2021 16:36:45 |

US3402284

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:25:19

[Narrative](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:37:27 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 17:32:34 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| User entered empty. | (b) (4) Tammy Kohn (b) (4) (b) (4) | 07 Apr 2021 16:36:45 |

US3402284

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:25:19

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:37:27 |
| User entered '0' | System | 07 Apr 2021 16:36:45 |

US3402284

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:25:19

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:37:27 |
| User entered '0' | System | 07 Apr 2021 16:36:45 |

US3402284

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:25:19

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:37:27 |

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:25:19

[AEID](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:37:32 |

US3402284

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:25:19

[Adverse event](#)

| Audit | User | Time (GMT) |
|---|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:37:32 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 17:32:40 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Muscle disorders, HLT: Muscle pains, PT: Myalgia, LLT: Muscle ache - version MedDRA\\23.0. | (b) (4) | |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 07 Apr 2021 16:40:48 |
| Data point term sent to Coder | (b) (4) | |
| User entered 'MUSCLE ACHES' | System | 07 Apr 2021 16:39:53 |
| | Tammy Kohn (b) (4) | 07 Apr 2021 16:39:33 |
| | (b) (4) | |

US3402284

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:25:19

[Was this a medically-attended AE?](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:37:32 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 17:32:48 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| User entered 'No (N)' | (b) (4) Tammy Kohn (b) (4) (b) (4) | 07 Apr 2021 16:39:33 |

US3402284

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:25:19

[Was this a Solicited Adverse Reaction?](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:37:32 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 17:32:49 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| User entered 'Yes (Y)' | (b) (4) Tammy Kohn (b) (4) (b) (4) | 07 Apr 2021 16:39:33 |

US3402284

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:25:19

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:37:32 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 17:32:51 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| User entered 'No (N)' | (b) (4) Tammy Kohn (b) (4) (b) (4) | 07 Apr 2021 16:39:33 |

US3402284

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:37:32 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 17:32:52 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| User entered '11 Sep 2020' | (b) (4) Tammy Kohn (b) (4) (b) (4) | 07 Apr 2021 16:39:33 |

US3402284

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:25:19

[Start time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:37:32 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 17:32:54 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| User entered '07:44' | (b) (4) Tammy Kohn (b) (4) (b) (4) | 07 Apr 2021 16:39:33 |

US3402284

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:25:19

[AE start date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:37:32 |
| User entered '11 Sep 2020 07:44' | System | 07 Apr 2021 16:39:33 |

US3402284

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:25:19

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:37:32 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 17:32:55 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| User entered 'No (N)' | (b) (4) Tammy Kohn (b) (4) (b) (4) | 07 Apr 2021 16:39:33 |

US3402284

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:25:19

If not Ongoing, end date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:37:32 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 17:32:57 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| User entered '02 Oct 2020' | (b) (4) Tammy Kohn (b) (4) (b) (4) | 07 Apr 2021 16:39:33 |

US3402284

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:25:19

[End time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:37:32 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 17:32:59 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| User entered '15:00' | (b) (4) Tammy Kohn (b) (4) (b) (4) | 07 Apr 2021 16:39:33 |

US3402284

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:25:19

[AE End Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:37:32 |
| User entered '02 Oct 2020 15:00' | System | 07 Apr 2021 16:39:33 |

US3402284

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:25:19

[Severity](#)

| Audit | User | Time (GMT) |
|--|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:37:32 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 17:33:01 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| User entered 'Grade 1/Mild (Grade 1/Mild)' | (b) (4) Tammy Kohn (b) (4) (b) (4) | 07 Apr 2021 16:39:33 |

US3402284

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:25:19

[Is the adverse event serious?](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:37:32 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 17:33:04 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| User entered 'No (N)' | (b) (4) Tammy Kohn (b) (4) (b) (4) | 07 Apr 2021 16:39:33 |

US3402284

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:25:19

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:37:32 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 17:33:07 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| User entered '0' | (b) (4) Tammy Kohn (b) (4) (b) (4) | 07 Apr 2021 16:39:33 |

US3402284

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:25:19

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:37:32 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 17:33:09 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| User entered '0' | (b) (4) Tammy Kohn (b) (4) (b) (4) | 07 Apr 2021 16:39:33 |

US3402284

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:25:19

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:37:32 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 17:33:11 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| User entered '0' | (b) (4) Tammy Kohn (b) (4) (b) (4) | 07 Apr 2021 16:39:33 |

US3402284

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:25:19

Hospital Admission Date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:37:32 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 17:33:12 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| User entered empty. | (b) (4) Tammy Kohn (b) (4) (b) (4) | 07 Apr 2021 16:39:33 |

US3402284

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:25:19

Hospital Discharge Date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:37:32 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 17:33:14 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| User entered empty. | (b) (4) Tammy Kohn (b) (4) (b) (4) | 07 Apr 2021 16:39:33 |

US3402284

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:25:19

[Admitted to ICU?](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:37:32 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 17:33:15 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| User entered empty. | (b) (4) Tammy Kohn (b) (4) (b) (4) | 07 Apr 2021 16:39:33 |

US3402284

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:25:19

[Number of Days in ICU](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:37:32 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 17:33:17 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| User entered empty. | (b) (4) Tammy Kohn (b) (4) (b) (4) | 07 Apr 2021 16:39:33 |

US3402284

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:25:19

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:37:32 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 17:33:19 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| User entered '0' | (b) (4) Tammy Kohn (b) (4) (b) (4) | 07 Apr 2021 16:39:33 |

US3402284

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:25:19

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:37:32 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 17:33:22 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| User entered '0' | (b) (4) Tammy Kohn (b) (4) (b) (4) | 07 Apr 2021 16:39:33 |

US3402284

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:25:19

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:37:32 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 17:33:24 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| User entered '0' | (b) (4) Tammy Kohn (b) (4) (b) (4) | 07 Apr 2021 16:39:33 |

US3402284

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:25:19

[Relationship to investigational product](#)

| Audit | User | Time (GMT) |
|----------------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:37:32 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 17:33:26 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| User entered 'Related (RELATED)' | (b) (4) Tammy Kohn (b) (4) (b) (4) | 07 Apr 2021 16:39:33 |

US3402284

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:25:19

[Relationship to Study Procedure](#)

| Audit | User | Time (GMT) |
|----------------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:37:32 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 17:33:27 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| User entered 'Related (RELATED)' | (b) (4) Tammy Kohn (b) (4) (b) (4) | 07 Apr 2021 16:39:33 |

US3402284

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:25:19

Action taken with investigational product

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:37:32 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 17:33:29 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| User closed query 'Data is required. Please complete.' (Site from System). | (b) (4) | |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 07 Apr 2021 16:40:09 |
| User entered 'None (NONE)' reason for change: Data Entry Error | System | 07 Apr 2021 16:40:09 |
| User opened query 'Data is required. Please complete.' (Site from System). | Tammy Kohn (b) (4) | 07 Apr 2021 16:40:09 |
| User entered empty. | (b) (4) | 07 Apr 2021 16:39:33 |
| | Tammy Kohn (b) (4) | 07 Apr 2021 16:39:33 |
| | (b) (4) | |

US3402284

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:25:19

[None](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:37:32 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 17:33:30 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| User entered 'l' | (b) (4) Tammy Kohn (b) (4) (b) (4) | 07 Apr 2021 16:39:33 |

US3402284

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:25:19

[Concomitant Medication](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:37:32 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 17:33:33 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| User entered '0' | (b) (4) Tammy Kohn (b) (4) (b) (4) | 07 Apr 2021 16:39:33 |

US3402284

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:25:19

[Concomitant Procedure](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:37:32 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 17:33:34 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| User entered '0' | (b) (4) Tammy Kohn (b) (4) (b) (4) | 07 Apr 2021 16:39:33 |

US3402284

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:25:19

[Outcome](#)

| Audit | User | Time (GMT) |
|---|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:37:32 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 17:33:36 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' | (b) (4) Tammy Kohn (b) (4) (b) (4) | 07 Apr 2021 16:39:33 |

US3402284

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:25:19

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:37:32 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 17:33:37 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| User entered empty. | (b) (4) Tammy Kohn (b) (4) (b) (4) | 07 Apr 2021 16:39:33 |

US3402284

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:25:19

[Narrative](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:37:32 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 17:33:39 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| User entered empty. | (b) (4) Tammy Kohn (b) (4) (b) (4) | 07 Apr 2021 16:39:33 |

US3402284

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:25:19

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:37:32 |
| User entered '0' | System | 07 Apr 2021 16:39:33 |

US3402284

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:25:19

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:37:32 |
| User entered '0' | System | 07 Apr 2021 16:39:33 |

US3402284

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:25:19

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 13:37:32 |
| | | |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|--|-------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 06:32:45 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| User closed query 'Per CDM re-query: Diary dose 2 Day 6 (15SEP) eDiary indicates Headache = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity. However there is no con med present for Headache for 15SEP per diary record. Please review if medication was taken. If yes, add the medication as appropriate else clarify in query response.' (Site from DM). | (b) (4) (b) (4), (b) (6) | 05 Mar 2021 05:46:10 |
| Query 'Per CDM re-query: Diary dose 2 Day 6 (15SEP) eDiary indicates Headache = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity. However there is no con med present for Headache for 15SEP per diary record. Please review if medication was taken. If yes, add the medication as appropriate else clarify in query response.' answered with 'UPDATED' (Site from DM). | Tammy Kohn (b) (4) (b) (4) | 04 Mar 2021 13:23:52 |
| User opened query 'Per CDM re-query: Diary dose 2 Day 6 (15SEP) eDiary indicates Headache = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity. However there is no con med present for Headache for 15SEP per diary record. Please review if medication was taken. If yes, add the medication as appropriate else clarify in query response.' (Site from DM). | (b) (4), (b) (6) | 03 Mar 2021 05:59:15 |
| User closed query 'Per DM CLR: Per Diary Dose 2 Day 6, Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' (Site from DM). | (b) (4), (b) (6) | 23 Feb 2021 10:45:13 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|--|-------------------------------|----------------------|
| Query 'Per DM CLR: Per Diary Dose 2 Day 6, Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' answered with 'DATA UPDATED' (Site from DM). | Tammy Kohn (b) (4) (b) (4) | 22 Feb 2021 16:44:14 |
| User opened query 'Per DM CLR: Per Diary Dose 2 Day 6, Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' | (b) (4), (b) (6) (b) (4) | 17 Feb 2021 12:57:30 |
| (Site from DM). DataPoint Verified. | (b) (4), (b) (6) (b) (4) | 20 Nov 2020 20:34:46 |
| User entered 'Yes (Y)' | Traci Hull (b) (4) (b) (4) | 08 Aug 2020 20:43:21 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:25:19

[Name of Medication](#)

| Audit | User | Time (GMT) |
|---|---------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 02 Oct 2020 19:01:48 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 02 Oct 2020 19:01:48 |
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, COMBINATIONS, ATC: MULTIVITAMINS WITH MINERALS, PRODUCT: ASCORBIC ACID;CALCIUM;MINERALS NOS;RETINOL;TOCOPHERYL ACETATE;VITAMIN B NOS;VITAMINS NOS;ZINC, PRODUCTSYNONYM: CENTRUM SILVER [ASCORBIC ACID;CALCIUM;MINERALS NOS;RETINOL;TOCOPHERYL ACETATE;VITAMIN B NOS;VITAMINS NOS;ZINC] - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 16 Sep 2020 05:30:56 |
| 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 Sep 2020 05:30:56 |
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 12 Aug 2020 16:06:10 |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:25:19

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--|--|--|
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. Data point term sent to Coder Coding entries removed. | Coder Import (b) (4) (b) (4) System Tarin Gordon (b) (4) (b) (4) | 12 Aug 2020 16:06:10 09 Aug 2020 13:45:34 09 Aug 2020 13:44:50 |
| User entered 'MULTIVITAMIN (CENTRUM SILVER)' reason for change: Data Entry Error User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003. | Tarin Gordon (b) (4) (b) (4) Coder Import (b) (4) (b) (4) | 09 Aug 2020 13:44:50 08 Aug 2020 20:45:51 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. Data point term sent to Coder User entered 'CENTRUM SILVER' | Coder Import (b) (4) (b) (4) System Traci Hull (b) (4) (b) (4) | 08 Aug 2020 20:45:51 08 Aug 2020 20:45:11 08 Aug 2020 20:44:17 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:25:19

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| User entered 'No (N)' | Traci Hull (b) (4) (b) (4) | 08 Aug 2020 20:44:17 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:25:19

[Indication](#)

| Audit | User | Time (GMT) |
|-----------------------------------|-------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| User entered 'DIETARY SUPPLEMENT' | Traci Hull (b) (4) (b) (4) | 08 Aug 2020 20:44:17 |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:25:19

[Dose per administration](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| | | |
| User entered '1' reason for change: Data Entry Error | Tarin Gordon (b) (4) | 09 Aug 2020 13:44:50 |
| | (b) (4) | |
| User entered '1000' | Traci Hull (b) (4) | 08 Aug 2020 20:44:17 |
| | (b) (4) | |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:25:19

[Dose unit](#)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| User entered 'tablet (TABLET)' reason for change: | Tarin Gordon (b) (4) | 09 Aug 2020 13:44:50 |
| Data Entry Error | (b) (4) | |
| User entered 'mg (mg)' | Traci Hull (b) (4) | 08 Aug 2020 20:44:17 |
| | (b) (4) | |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:25:19

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| | | |
| User entered empty. | Traci Hull (b) (4) | 08 Aug 2020 20:44:17 |
| | (b) (4) | |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:25:19

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|-------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| User entered 'once daily (QD)' | Traci Hull (b) (4) (b) (4) | 08 Aug 2020 20:44:17 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:25:19

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| User entered empty. | Traci Hull (b) (4) (b) (4) | 08 Aug 2020 20:44:17 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:25:19

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| | | |
| User entered 'Oral (ORAL)' | Traci Hull (b) (4) | 08 Aug 2020 20:44:17 |
| | (b) (4) | |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:25:19

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| User entered empty. | Traci Hull (b) (4) (b) (4) | 08 Aug 2020 20:44:17 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:25:19

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| | | |
| User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). | (b) (4), (b) (6) | 15 Aug 2020 17:40:07 |
| 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.' | Traci Hull (b) (4) | 08 Aug 2020 20:47:34 |
| answered with 'ON GOING' (Site from System). | (b) (4) | |
| 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 | 08 Aug 2020 20:44:17 |
| User entered 'UN UNK 2000' | Traci Hull (b) (4) | 08 Aug 2020 20:44:17 |
| | (b) (4) | |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:25:19

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| User entered '0' | Traci Hull (b) (4) (b) (4) | 08 Aug 2020 20:44:17 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:25:19

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| User entered 'Yes (Y)' | Traci Hull (b) (4) (b) (4) | 08 Aug 2020 20:44:17 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:25:19

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| User entered empty. | Traci Hull (b) (4) (b) (4) | 08 Aug 2020 20:44:17 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:25:19

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| | | |
| User entered 'No (N)' | Traci Hull (b) (4) | 08 Aug 2020 20:44:17 |
| | (b) (4) | |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:25:19

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 08 Aug 2020 20:44:17 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:25:19

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 08 Aug 2020 20:44:17 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:25:19

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 08 Aug 2020 20:44:17 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:25:19

Name of Medication

| Audit | User | Time (GMT) |
|--|---------------------------------|--|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| 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) (b) (4) | 09 Oct 2020 00:06:01 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 09 Oct 2020 00:06:01 |
| Data point term sent to Coder Coding entries removed. | System Traci Hull (b) (4) | 08 Oct 2020 20:40:09 08 Oct 2020 20:39:23 |
| 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) (b) (4) | 10 Sep 2020 14:06:48 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 10 Sep 2020 14:06:48 |
| Data point term sent to Coder | System | 10 Sep 2020 13:18:11 |
| Data point term sent to Coder | System | 10 Sep 2020 13:17:10 |
| Coding entries removed. | Tammy Kohn (b) (4) (b) (4) | 10 Sep 2020 13:16:30 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:25:19

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| 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) | 09 Aug 2020 14:01:29 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 09 Aug 2020 14:01:29 |
| Data point term sent to Coder | System | 09 Aug 2020 14:00:39 |
| Data point term sent to Coder | System | 08 Aug 2020 20:45:11 |
| User entered 'ASPIRIN' | Traci Hull (b) (4) | 08 Aug 2020 20:44:51 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:25:19

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|--|-------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| User closed query 'Per CDM: Indication has been updated to Cardiac Prophylaxis however response to Prophylaxis is NO. Please review and update as appropriate.' (Site from DM). | (b) (4), (b) (6) | 21 Oct 2020 12:00:59 |
| Query 'Per CDM: Indication has been updated to Cardiac Prophylaxis however response to Prophylaxis is NO. Please review and update as appropriate.' answered with 'DATA UPDATED' (Site from DM). | Tammy Kohn (b) (4) (b) (4) | 20 Oct 2020 13:42:55 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | Tammy Kohn (b) (4) (b) (4) | 20 Oct 2020 13:42:48 |
| User opened query 'Per CDM: Indication has been updated to Cardiac Prophylaxis however response to Prophylaxis is NO. Please review and update as appropriate.' (Site from DM). | (b) (4), (b) (6) | 19 Oct 2020 14:45:37 |
| User closed query 'Per CDM: it appears this medication was used for prophylaxis; however, it is not recorded as Prohylaxis. Please review, reconcile, and update accordingly.' (Site from DM). | (b) (4), (b) (6) | 10 Sep 2020 15:14:28 |
| Query 'Per CDM: it appears this medication was used for prophylaxis; however, it is not recorded as Prohylaxis. Please review, reconcile, and update accordingly.' answered with 'Prevent Heart Attack.' (Site from DM). | Tammy Kohn (b) (4) (b) (4) | 10 Sep 2020 13:14:33 |
| User opened query 'Per CDM: it appears this medication was used for prophylaxis; however, it is not recorded as Prohylaxis. Please review, reconcile, and update accordingly.' (Site from DM). | (b) (4), (b) (6) | 05 Sep 2020 11:10:08 |
| User entered 'No (N)' | Traci Hull (b) (4) (b) (4) | 08 Aug 2020 20:44:51 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:25:19

[Indication](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM). | (b) (4), (b) (6) | 19 Oct 2020 14:45:29 |
| Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' answered with 'UPDATED' (Site from DM). | Traci Hull (b) (4) (b) (4) | 08 Oct 2020 20:39:31 |
| User entered 'CARDIAC PROPHYLAXIS' reason for change: Per Query Resolution | Traci Hull (b) (4) (b) (4) | 08 Oct 2020 20:39:23 |
| User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM). | (b) (4), (b) (6) | 02 Oct 2020 04:38:11 |
| User entered 'CARDIAC EVENT' reason for change: Data Entry Error | Tammy Kohn (b) (4) (b) (4) | 10 Sep 2020 13:17:11 |
| User entered 'Prevent cardiac event' reason for change: Data Entry Error | Tammy Kohn (b) (4) (b) (4) | 10 Sep 2020 13:16:30 |
| User entered 'CARDIAC PROPHYLAXIS' reason for change: Data Entry Error | Tarin Gordon (b) (4) (b) (4) | 09 Aug 2020 13:59:47 |
| User entered 'BLOOD THINNER' | Traci Hull (b) (4) (b) (4) | 08 Aug 2020 20:44:51 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:25:19

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| User entered '81' | Traci Hull (b) (4) (b) (4) | 08 Aug 2020 20:44:51 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:25:19

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| User entered 'mg (mg)' | Traci Hull (b) (4) (b) (4) | 08 Aug 2020 20:44:51 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:25:19

[If dose unit is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| User entered empty. | Traci Hull (b) (4) (b) (4) | 08 Aug 2020 20:44:51 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:25:19

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|-------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| User entered 'once daily (QD)' | Traci Hull (b) (4) (b) (4) | 08 Aug 2020 20:44:51 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:25:19

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| User entered empty. | Traci Hull (b) (4) (b) (4) | 08 Aug 2020 20:44:51 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:25:19

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| User entered 'Oral (ORAL)' | Traci Hull (b) (4) (b) (4) | 08 Aug 2020 20:44:51 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:25:19

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| User entered empty. | Traci Hull (b) (4) (b) (4) | 08 Aug 2020 20:44:51 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:25:19

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| | | |
| User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). | (b) (4), (b) (6) | 15 Aug 2020 17:40:13 |
| 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.' | Traci Hull (b) (4) | 08 Aug 2020 20:47:27 |
| answered with 'ON GOING' (Site from System). | (b) (4) | |
| 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 | 08 Aug 2020 20:44:51 |
| User entered 'UN UNK 2000' | Traci Hull (b) (4) | 08 Aug 2020 20:44:51 |
| | (b) (4) | |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:25:19

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| User entered '0' | Traci Hull (b) (4) (b) (4) | 08 Aug 2020 20:44:51 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:25:19

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| User entered 'Yes (Y)' | Traci Hull (b) (4) (b) (4) | 08 Aug 2020 20:44:51 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:25:19

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| User entered empty. | Traci Hull (b) (4) (b) (4) | 08 Aug 2020 20:44:51 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:25:19

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| User entered 'No (N)' | Traci Hull (b) (4) (b) (4) | 08 Aug 2020 20:44:51 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:25:19

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 08 Aug 2020 20:44:51 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:25:19

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 08 Aug 2020 20:44:51 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:25:19

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 08 Aug 2020 20:44:51 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:25:19

[Name of Medication](#)

| Audit | User | Time (GMT) |
|---|----------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| | | |
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: BIGUANIDES, PRODUCT: METFORMIN - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 08 Aug 2020 20:46:51 |
| | (b) (4) | |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 08 Aug 2020 20:46:51 |
| | (b) (4) | |
| Data point term sent to Coder | System | 08 Aug 2020 20:46:11 |
| User entered 'METFORMIN' | Traci Hull (b) (4) | 08 Aug 2020 20:45:29 |
| | (b) (4) | |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:25:19

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| User entered 'No (N)' | Traci Hull (b) (4) (b) (4) | 08 Aug 2020 20:45:29 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:25:19

[Indication](#)

| Audit | User | Time (GMT) |
|--------------------------------|-------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| User entered 'TYPE 2 DIABETES' | Traci Hull (b) (4) (b) (4) | 08 Aug 2020 20:45:29 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:25:19

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| User entered '500' | Traci Hull (b) (4) (b) (4) | 08 Aug 2020 20:45:29 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:25:19

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| User entered 'mg (mg)' | Traci Hull (b) (4) (b) (4) | 08 Aug 2020 20:45:29 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:25:19

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| User entered empty. | Traci Hull (b) (4) (b) (4) | 08 Aug 2020 20:45:29 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:25:19

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|-------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| User entered 'once daily (QD)' | Traci Hull (b) (4) (b) (4) | 08 Aug 2020 20:45:29 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:25:19

If frequency is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| User entered empty. | Traci Hull (b) (4) (b) (4) | 08 Aug 2020 20:45:29 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:25:19

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|-------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| User entered 'Oral (ORAL)' | Traci Hull (b) (4) (b) (4) | 08 Aug 2020 20:45:29 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:25:19

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| User entered empty. | Traci Hull (b) (4) (b) (4) | 08 Aug 2020 20:45:29 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:25:19

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| | | |
| User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). | (b) (4), (b) (6) | 15 Aug 2020 17:40:16 |
| 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.' | Traci Hull (b) (4) | 08 Aug 2020 20:47:19 |
| answered with 'ON GOING' (Site from System). | (b) (4) | |
| 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 | 08 Aug 2020 20:45:29 |
| User entered 'UN UNK 2019' | Traci Hull (b) (4) | 08 Aug 2020 20:45:29 |
| | (b) (4) | |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:25:19

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| User entered '0' | Traci Hull (b) (4) (b) (4) | 08 Aug 2020 20:45:29 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:25:19

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| User entered 'Yes (Y)' | Traci Hull (b) (4) (b) (4) | 08 Aug 2020 20:45:29 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:25:19

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| User entered empty. | Traci Hull (b) (4) (b) (4) | 08 Aug 2020 20:45:29 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:25:19

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| User entered 'No (N)' | Traci Hull (b) (4) (b) (4) | 08 Aug 2020 20:45:29 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:25:19

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 08 Aug 2020 20:45:29 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:25:19

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 08 Aug 2020 20:45:29 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:25:19

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 08 Aug 2020 20:45:29 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:25:19

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| | | |
| User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 08 Aug 2020 20:46:51 |
| | (b) (4) | |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 08 Aug 2020 20:46:51 |
| | (b) (4) | |
| Data point term sent to Coder User entered 'METOPROLOL' | System | 08 Aug 2020 20:46:12 |
| | Traci Hull (b) (4) | 08 Aug 2020 20:46:06 |
| | (b) (4) | |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:25:19

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| | | |
| User entered 'No (N)' | Traci Hull (b) (4) | 08 Aug 2020 20:46:06 |
| | (b) (4) | |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:25:19

[Indication](#)

| Audit | User | Time (GMT) |
|-----------------------------|-------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| User entered 'HYPERTENSION' | Traci Hull (b) (4) (b) (4) | 08 Aug 2020 20:46:06 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:25:19

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| | | |
| User entered '100' | Traci Hull (b) (4) | 08 Aug 2020 20:46:06 |
| | (b) (4) | |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:25:19

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| User entered 'mg (mg)' | Traci Hull (b) (4) (b) (4) | 08 Aug 2020 20:46:06 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:25:19

[If dose unit is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| | | |
| User entered empty. | Traci Hull (b) (4) | 08 Aug 2020 20:46:06 |
| | (b) (4) | |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:25:19

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|-------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| User entered 'once daily (QD)' | Traci Hull (b) (4) (b) (4) | 08 Aug 2020 20:46:06 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:25:19

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| User entered empty. | Traci Hull (b) (4) (b) (4) | 08 Aug 2020 20:46:06 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:25:19

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| | | |
| User entered 'Oral (ORAL)' | Traci Hull (b) (4) | 08 Aug 2020 20:46:06 |
| | (b) (4) | |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:25:19

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| User entered empty. | Traci Hull (b) (4) (b) (4) | 08 Aug 2020 20:46:06 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:25:19

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|-------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| User closed query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate. ' (Site from DM). | (b) (4), (b) (6) | 30 Sep 2020 18:21:14 |
| Query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate. ' answered with 'DATA UPDATED' (Site from DM). | Tammy Kohn (b) (4) (b) (4) | 26 Sep 2020 15:02:01 |
| User entered 'UN UNK 2017' reason for change: Data Entry Error | Tammy Kohn (b) (4) (b) (4) | 26 Sep 2020 15:01:46 |
| User opened query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate. ' (Site from DM). | (b) (4), (b) (6) | 23 Sep 2020 02:11:15 |
| User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). | (b) (4), (b) (6) | 15 Aug 2020 17:40:20 |
| 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 'ON GOING' (Site from System). | Traci Hull (b) (4) (b) (4) | 08 Aug 2020 20:47:13 |
| 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 | 08 Aug 2020 20:46:06 |
| User entered 'UN UNK 2010' | Traci Hull (b) (4) (b) (4) | 08 Aug 2020 20:46:06 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:25:19

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| User entered '0' | Traci Hull (b) (4) (b) (4) | 08 Aug 2020 20:46:06 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:25:19

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| User entered 'Yes (Y)' | Traci Hull (b) (4) (b) (4) | 08 Aug 2020 20:46:06 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:25:19

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| User entered empty. | Traci Hull (b) (4) (b) (4) | 08 Aug 2020 20:46:06 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:25:19

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| User entered 'No (N)' | Traci Hull (b) (4) (b) (4) | 08 Aug 2020 20:46:06 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:25:19

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 08 Aug 2020 20:46:06 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:25:19

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 08 Aug 2020 20:46:06 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:25:19

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 08 Aug 2020 20:46:06 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:25:19

Name of Medication

| Audit | User | Time (GMT) |
|---|----------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| | | |
| Query 'Per source please verify and update if this is used as a combo drug with Hydrochlorothiazide, 12.5mg. ' canceled (Site from CRA). | (b) (4), (b) (6) | 20 Nov 2020 20:38:57 |
| | | |
| User opened query 'Per source please verify and update if this is used as a combo drug with Hydrochlorothiazide, 12.5mg. ' (Site from CRA). | (b) (4), (b) (6) | 20 Nov 2020 20:37:15 |
| | | |
| User coded data point as ATC: | Coder Import (b) (4) | 26 Sep 2020 15:06:43 |
| CARDIOVASCULAR SYSTEM, ATC: AGENTS | (b) (4) | |
| ACTING ON THE RENIN-ANGIOTENSIN | | |
| SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: | | |
| ACE INHIBITORS, PLAIN, PRODUCT: | | |
| BENAZEPRIL - version | | |
| WHODrug-Global-B3\202003. | | |
| User coded data point as Term Coded data point by | Coder Import (b) (4) | 26 Sep 2020 15:06:43 |
| User: Coder System - version | (b) (4) | |
| WHODrug-Global-B3\202003. | | |
| Data point term sent to Coder | System | 26 Sep 2020 15:05:19 |
| Coding entries removed. | Tammy Kohn (b) (4) | 26 Sep 2020 15:04:32 |
| | (b) (4) | |
| User entered 'BENAZEPRIL' reason for change: | Tammy Kohn (b) (4) | 26 Sep 2020 15:04:32 |
| Data Entry Error | (b) (4) | |
| User coded data point as ATC: | Coder Import (b) (4) | 11 Aug 2020 06:50:32 |
| CARDIOVASCULAR SYSTEM, ATC: AGENTS | (b) (4) | |
| ACTING ON THE RENIN-ANGIOTENSIN | | |
| SYSTEM, ATC: ACE INHIBITORS, | | |
| COMBINATIONS, ATC: ACE INHIBITORS AND | | |
| DIURETICS, PRODUCT: | | |
| BENAZEPRIL;HYDROCHLOROTHIAZIDE - | | |
| version WHODrug-Global-B3\202003. | | |
| User coded data point as Term Coded data point by | Coder Import (b) (4) | 11 Aug 2020 06:50:32 |
| User: (b) (6) - version | (b) (4) | |
| WHODrug-Global-B3\202003. | | |
| Data point term sent to Coder | System | 09 Aug 2020 13:58:38 |
| User entered 'BENAZEPRIL/ | Tarin Gordon (b) (4) | 09 Aug 2020 13:58:31 |
| HYDROCHLOROTHIAZIDE' reason for change: | (b) (4) | |
| Data Entry Error | | |
| Data point term sent to Coder | System | 08 Aug 2020 20:47:13 |

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:25:19

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--|-------------------------------|----------------------|
| User entered 'BIZNAZPRIL HYDROCHLOROTHIAZIDE' | Traci Hull (b) (4) (b) (4) | 08 Aug 2020 20:46:40 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:25:19

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| User entered 'No (N)' | Traci Hull (b) (4) (b) (4) | 08 Aug 2020 20:46:40 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:25:19

[Indication](#)

| Audit | User | Time (GMT) |
|-----------------------------|-------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| User entered 'HYPERTENSION' | Traci Hull (b) (4) (b) (4) | 08 Aug 2020 20:46:40 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:25:19

[Dose per administration](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| | | |
| User entered '20' reason for change: Data Entry Error | Tammy Kohn (b) (4) | 26 Sep 2020 15:04:32 |
| | (b) (4) | |
| User entered '20/12.5' reason for change: Data Entry Error | Tarin Gordon (b) (4) | 09 Aug 2020 13:58:31 |
| | (b) (4) | |
| User entered '20' | Traci Hull (b) (4) | 08 Aug 2020 20:46:40 |
| | (b) (4) | |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:25:19

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| User entered 'mg (mg)' | Traci Hull (b) (4) (b) (4) | 08 Aug 2020 20:46:40 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:25:19

[If dose unit is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| User entered empty. | Traci Hull (b) (4) (b) (4) | 08 Aug 2020 20:46:40 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:25:19

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|-------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| User entered 'once daily (QD)' | Traci Hull (b) (4) (b) (4) | 08 Aug 2020 20:46:40 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:25:19

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| User entered empty. | Traci Hull (b) (4) (b) (4) | 08 Aug 2020 20:46:40 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:25:19

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| | | |
| User entered 'Oral (ORAL)' | Traci Hull (b) (4) | 08 Aug 2020 20:46:40 |
| | (b) (4) | |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:25:19

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| User entered empty. | Traci Hull (b) (4) (b) (4) | 08 Aug 2020 20:46:40 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:25:19

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|-------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| User closed query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate. ' (Site from DM). | (b) (4), (b) (6) | 30 Sep 2020 18:21:45 |
| Query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate. ' answered with 'DATA UPDATED' (Site from DM). | Tammy Kohn (b) (4) (b) (4) | 26 Sep 2020 15:07:15 |
| User opened query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate. ' (Site from DM). | (b) (4), (b) (6) | 23 Sep 2020 02:10:22 |
| User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). | (b) (4), (b) (6) | 15 Aug 2020 17:40:27 |
| 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 'ON GOING' (Site from System). | Traci Hull (b) (4) (b) (4) | 08 Aug 2020 20:47:05 |
| 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 | 08 Aug 2020 20:46:40 |
| User entered 'UN UNK 2000' | Traci Hull (b) (4) (b) (4) | 08 Aug 2020 20:46:40 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:25:19

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| User entered '0' | Traci Hull (b) (4) (b) (4) | 08 Aug 2020 20:46:40 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:25:19

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| User entered 'Yes (Y)' | Traci Hull (b) (4) (b) (4) | 08 Aug 2020 20:46:40 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:25:19

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| User entered empty. | Traci Hull (b) (4) (b) (4) | 08 Aug 2020 20:46:40 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:25:19

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| User entered 'No (N)' | Traci Hull (b) (4) (b) (4) | 08 Aug 2020 20:46:40 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:25:19

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 08 Aug 2020 20:46:40 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:25:19

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 08 Aug 2020 20:46:40 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:25:19

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 08 Aug 2020 20:46:40 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:25:19

Name of Medication

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| | | |
| User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: NAPROXEN - version WHODrug-Global-B3\202003. | Coder Import (b) (4) | 28 Sep 2020 03:46:55 |
| | (b) (4) | |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003. | Coder Import (b) (4) | 28 Sep 2020 03:46:55 |
| | (b) (4) | |
| Data point term sent to Coder | System | 26 Sep 2020 15:03:16 |
| Coding entries removed. | Tammy Kohn (b) (4) | 26 Sep 2020 15:02:41 |
| | (b) (4) | |
| User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: NAPROXEN - version WHODrug-Global-B3\202003. | Coder Import (b) (4) | 09 Aug 2020 14:03:31 |
| | (b) (4) | |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003. | Coder Import (b) (4) | 09 Aug 2020 14:03:31 |
| | (b) (4) | |
| Data point term sent to Coder | System | 09 Aug 2020 14:02:39 |
| User entered 'NAPROXEN' | Tarin Gordon (b) (4) | 09 Aug 2020 14:01:56 |
| | (b) (4) | |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:25:19

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| | | |
| User entered 'No (N)' | Tarin Gordon (b) (4) | 09 Aug 2020 14:01:56 |
| | (b) (4) | |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:25:19

[Indication](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| | | |
| User closed query 'Per DM CLR: Please update the indication to reflect the location of OSTEOARTHRITIS (e.g., Generalized, Both Knees, Right Hip, etc). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. | (b) (4), (b) (6) | 01 Oct 2020 12:56:28 |
| ' (Site from DM). | | |
| User entered 'OSTEOARTHRITIS LEFT HIP' reason for change: Data Entry Error | Tammy Kohn (b) (4) | 26 Sep 2020 15:02:41 |
| | (b) (4) | |
| Query 'Per DM CLR: Please update the indication to reflect the location of OSTEOARTHRITIS (e.g., Generalized, Both Knees, Right Hip, etc). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. | Tammy Kohn (b) (4) | 26 Sep 2020 15:02:27 |
| ' answered with 'LEFT HIP' (Site from DM). | (b) (4) | |
| User opened query 'Per DM CLR: Please update the indication to reflect the location of OSTEOARTHRITIS (e.g., Generalized, Both Knees, Right Hip, etc). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. | (b) (4), (b) (6) | 23 Sep 2020 02:11:54 |
| ' (Site from DM). | | |
| User entered 'OSTEOARTHRITIS' | Tarin Gordon (b) (4) | 09 Aug 2020 14:01:56 |
| | (b) (4) | |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:25:19

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| | | |
| User entered '500' | Tarin Gordon (b) (4) | 09 Aug 2020 14:01:56 |
| | (b) (4) | |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:25:19

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| User entered 'mg (mg)' | Tarin Gordon (b) (4) (b) (4) | 09 Aug 2020 14:01:56 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:25:19

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| User entered empty. | Tarin Gordon (b) (4) (b) (4) | 09 Aug 2020 14:01:56 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:25:19

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|----------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| | | |
| User entered 'once daily (QD)' | Tarin Gordon (b) (4) | 09 Aug 2020 14:01:56 |
| | (b) (4) | |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:25:19

If frequency is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| User entered empty. | Tarin Gordon (b) (4) (b) (4) | 09 Aug 2020 14:01:56 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:25:19

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| User entered 'Oral (ORAL)' | Tarin Gordon (b) (4) (b) (4) | 09 Aug 2020 14:01:56 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:25:19

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| User entered empty. | Tarin Gordon (b) (4) (b) (4) | 09 Aug 2020 14:01:56 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:25:19

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| | | |
| User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). | (b) (4), (b) (6) | 15 Aug 2020 17:40:32 |
| 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.' | Tarin Gordon (b) (4) | 09 Aug 2020 14:23:15 |
| answered with 'ONGOING' (Site from System). | (b) (4) | |
| 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 | 09 Aug 2020 14:01:56 |
| User entered 'UN UNK 1982' | Tarin Gordon (b) (4) | 09 Aug 2020 14:01:56 |
| | (b) (4) | |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:25:19

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| | | |
| User entered '0' | Tarin Gordon (b) (4) | 09 Aug 2020 14:01:56 |
| | (b) (4) | |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:25:19

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| User entered 'Yes (Y)' | Tarin Gordon (b) (4) (b) (4) | 09 Aug 2020 14:01:56 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:25:19

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| User entered empty. | Tarin Gordon (b) (4) (b) (4) | 09 Aug 2020 14:01:56 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:25:19

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| User entered 'No (N)' | Tarin Gordon (b) (4) (b) (4) | 09 Aug 2020 14:01:56 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:25:19

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 09 Aug 2020 14:01:56 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:25:19

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 09 Aug 2020 14:01:56 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:25:19

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 09 Aug 2020 14:01:56 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:25:19

[Name of Medication](#)

| Audit | User | Time (GMT) |
|---|---------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: OTHER CENTRALLY ACTING AGENTS, PRODUCT: CYCLOBENZAPRINE - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 11 Aug 2020 11:35:07 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 11 Aug 2020 11:35:07 |
| Data point term sent to Coder | System | 09 Aug 2020 14:03:40 |
| User entered 'CYCLOBENZAPRINE' | Tarin Gordon (b) (4) (b) (4) | 09 Aug 2020 14:02:40 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:25:19

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| User entered 'No (N)' | Tarin Gordon (b) (4) (b) (4) | 09 Aug 2020 14:02:40 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:25:19

[Indication](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| User entered 'PINCHED NERVE LEFT SHOULDER' | Tarin Gordon (b) (4) (b) (4) | 09 Aug 2020 14:02:40 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:25:19

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| | | |
| User entered '10' | Tarin Gordon (b) (4) | 09 Aug 2020 14:02:40 |
| | (b) (4) | |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:25:19

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| User entered 'mg (mg)' | Tarin Gordon (b) (4) (b) (4) | 09 Aug 2020 14:02:40 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:25:19

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| User entered empty. | Tarin Gordon (b) (4) (b) (4) | 09 Aug 2020 14:02:40 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:25:19

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|----------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| | | |
| User entered 'once daily (QD)' | Tarin Gordon (b) (4) | 09 Aug 2020 14:02:40 |
| | (b) (4) | |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:25:19

If frequency is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| User entered empty. | Tarin Gordon (b) (4) (b) (4) | 09 Aug 2020 14:02:40 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:25:19

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| | | |
| User entered 'Oral (ORAL)' | Tarin Gordon (b) (4) | 09 Aug 2020 14:02:40 |
| | (b) (4) | |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:25:19

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| User entered empty. | Tarin Gordon (b) (4) (b) (4) | 09 Aug 2020 14:02:40 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:25:19

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| | | |
| User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). | (b) (4), (b) (6) | 15 Aug 2020 17:40:35 |
| 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.' | Tarin Gordon (b) (4) | 09 Aug 2020 14:23:07 |
| answered with 'ONGOING' (Site from System). | (b) (4) | |
| 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 | 09 Aug 2020 14:02:40 |
| User entered 'UN Feb 2020' | Tarin Gordon (b) (4) | 09 Aug 2020 14:02:40 |
| | (b) (4) | |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:25:19

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| User entered '0' | Tarin Gordon (b) (4) (b) (4) | 09 Aug 2020 14:02:40 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:25:19

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| User entered 'Yes (Y)' | Tarin Gordon (b) (4) (b) (4) | 09 Aug 2020 14:02:40 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:25:19

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| User entered empty. | Tarin Gordon (b) (4) (b) (4) | 09 Aug 2020 14:02:40 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:25:19

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| User entered 'No (N)' | Tarin Gordon (b) (4) (b) (4) | 09 Aug 2020 14:02:40 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:25:19

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 09 Aug 2020 14:02:40 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:25:19

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 09 Aug 2020 14:02:40 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:25:19

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 09 Aug 2020 14:02:40 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:25:19

[Name of Medication](#)

| Audit | User | Time (GMT) |
|---|---|--|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN CALCIUM - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 09 Aug 2020 14:04:31 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 09 Aug 2020 14:04:31 |
| Data point term sent to Coder User entered 'ATORVASTATIN CALCIUM' | System Tarin Gordon (b) (4) (b) (4) | 09 Aug 2020 14:03:40 09 Aug 2020 14:03:17 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:25:19

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| User entered 'No (N)' | Tarin Gordon (b) (4) (b) (4) | 09 Aug 2020 14:03:17 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:25:19

[Indication](#)

| Audit | User | Time (GMT) |
|-------------------------------------|---------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| User entered 'HYPERCHOLESTEROLEMIA' | Tarin Gordon (b) (4) (b) (4) | 09 Aug 2020 14:03:17 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:25:19

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| User entered '10' | Tarin Gordon (b) (4) (b) (4) | 09 Aug 2020 14:03:17 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:25:19

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| User entered 'mg (mg)' | Tarin Gordon (b) (4) (b) (4) | 09 Aug 2020 14:03:17 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:25:19

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| User entered empty. | Tarin Gordon (b) (4) (b) (4) | 09 Aug 2020 14:03:17 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:25:19

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|----------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| | | |
| User entered 'once daily (QD)' | Tarin Gordon (b) (4) | 09 Aug 2020 14:03:17 |
| | (b) (4) | |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:25:19

If frequency is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| User entered empty. | Tarin Gordon (b) (4) (b) (4) | 09 Aug 2020 14:03:17 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:25:19

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| | | |
| User entered 'Oral (ORAL)' | Tarin Gordon (b) (4) | 09 Aug 2020 14:03:17 |
| | (b) (4) | |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:25:19

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| User entered empty. | Tarin Gordon (b) (4) (b) (4) | 09 Aug 2020 14:03:17 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:25:19

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| | | |
| User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). | (b) (4), (b) (6) | 15 Aug 2020 17:40:43 |
| 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.' | Tarin Gordon (b) (4) | 09 Aug 2020 14:23:02 |
| answered with 'ONGOING' (Site from System). | (b) (4) | |
| 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 | 09 Aug 2020 14:03:17 |
| User entered 'UN May 2020' | Tarin Gordon (b) (4) | 09 Aug 2020 14:03:17 |
| | (b) (4) | |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:25:19

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| User entered '0' | Tarin Gordon (b) (4) (b) (4) | 09 Aug 2020 14:03:17 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:25:19

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| User entered 'Yes (Y)' | Tarin Gordon (b) (4) (b) (4) | 09 Aug 2020 14:03:17 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:25:19

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| User entered empty. | Tarin Gordon (b) (4) (b) (4) | 09 Aug 2020 14:03:17 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:25:19

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| User entered 'No (N)' | Tarin Gordon (b) (4) (b) (4) | 09 Aug 2020 14:03:17 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:25:19

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 09 Aug 2020 14:03:17 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:25:19

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 09 Aug 2020 14:03:17 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:25:19

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 09 Aug 2020 14:03:17 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:25:19

[Name of Medication](#)

| Audit | User | Time (GMT) |
|---|---|--|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIGOUT PREPARATIONS, ATC: ANTIGOUT PREPARATIONS, ATC: PREPARATIONS INHIBITING URIC ACID PRODUCTION, PRODUCT: ALLOPURINOL - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 09 Aug 2020 14:05:31 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 09 Aug 2020 14:05:31 |
| Data point term sent to Coder User entered 'ALLOPURINOL' | System Tarin Gordon (b) (4) (b) (4) | 09 Aug 2020 14:04:40 09 Aug 2020 14:03:46 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:25:19

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| User entered 'No (N)' | Tarin Gordon (b) (4) (b) (4) | 09 Aug 2020 14:03:46 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:25:19

[Indication](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| User closed query 'Per DM CLR: Please update the indication to reflect the location of GOUT (e.g., Generalized, Both Hips, Right Knee, etc). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM). | (b) (4), (b) (6) | 02 Oct 2020 17:40:30 |
| Query 'Per DM CLR: Please update the indication to reflect the location of GOUT (e.g., Generalized, Both Hips, Right Knee, etc). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. | Tammy Kohn (b) (4) (b) (4) | 26 Sep 2020 15:12:39 |
| ' answered with 'RIGHT FOOT' (Site from DM). User opened query 'Per DM CLR: Please update the indication to reflect the location of GOUT (e.g., Generalized, Both Hips, Right Knee, etc). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM). | (b) (4), (b) (6) | 23 Sep 2020 02:09:02 |
| User entered 'GOUT' | Tarin Gordon (b) (4) (b) (4) | 09 Aug 2020 14:03:46 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:25:19

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| | | |
| User entered '300' | Tarin Gordon (b) (4) | 09 Aug 2020 14:03:46 |
| | (b) (4) | |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:25:19

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| User entered 'mg (mg)' | Tarin Gordon (b) (4) (b) (4) | 09 Aug 2020 14:03:46 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:25:19

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| | | |
| User entered empty. | Tarin Gordon (b) (4) | 09 Aug 2020 14:03:46 |
| | (b) (4) | |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:25:19

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|----------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| | | |
| User entered 'once daily (QD)' | Tarin Gordon (b) (4) | 09 Aug 2020 14:03:46 |
| | (b) (4) | |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:25:19

If frequency is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| User entered empty. | Tarin Gordon (b) (4) (b) (4) | 09 Aug 2020 14:03:46 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:25:19

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| User entered 'Oral (ORAL)' | Tarin Gordon (b) (4) (b) (4) | 09 Aug 2020 14:03:46 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:25:19

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| User entered empty. | Tarin Gordon (b) (4) (b) (4) | 09 Aug 2020 14:03:46 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:25:19

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| | | |
| User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). | (b) (4), (b) (6) | 15 Aug 2020 17:40:47 |
| 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.' | Tarin Gordon (b) (4) | 09 Aug 2020 14:22:56 |
| answered with 'ONGOING' (Site from System). | (b) (4) | |
| 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 | 09 Aug 2020 14:03:46 |
| User entered 'UN UNK 2005' | Tarin Gordon (b) (4) | 09 Aug 2020 14:03:46 |
| | (b) (4) | |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:25:19

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| User entered '0' | Tarin Gordon (b) (4) (b) (4) | 09 Aug 2020 14:03:46 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:25:19

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| User entered 'Yes (Y)' | Tarin Gordon (b) (4) (b) (4) | 09 Aug 2020 14:03:46 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:25:19

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| User entered empty. | Tarin Gordon (b) (4) (b) (4) | 09 Aug 2020 14:03:46 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:25:19

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| User entered 'No (N)' | Tarin Gordon (b) (4) (b) (4) | 09 Aug 2020 14:03:46 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:25:19

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 09 Aug 2020 14:03:46 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:25:19

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 09 Aug 2020 14:03:46 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:25:19

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 09 Aug 2020 14:03:46 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:25:19

[Name of Medication](#)

| Audit | User | Time (GMT) |
|---|---------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: CORTICOSTEROIDS, PRODUCT: FLUTICASONE PROPIONATE - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 10 Sep 2020 14:36:40 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 10 Sep 2020 14:36:40 |
| Data point term sent to Coder | System | 10 Sep 2020 13:29:34 |
| Coding entries removed. | Tammy Kohn (b) (4) (b) (4) | 10 Sep 2020 13:29:28 |
| User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, INHALANTS, ATC: GLUCOCORTICOIDS, PRODUCT: FLUTICASONE PROPIONATE - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 14 Aug 2020 06:47:14 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 14 Aug 2020 06:47:14 |
| Data point term sent to Coder | System | 09 Aug 2020 14:05:41 |
| User entered 'FLUTICASONE PROPIONATE' | Tarin Gordon (b) (4) (b) (4) | 09 Aug 2020 14:04:58 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:25:19

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| User entered 'No (N)' | Tarin Gordon (b) (4) (b) (4) | 09 Aug 2020 14:04:58 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:25:19

[Indication](#)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| User entered 'SLEEP APNEA' | Tarin Gordon (b) (4) (b) (4) | 09 Aug 2020 14:04:58 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:25:19

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| | | |
| User entered '50' | Tarin Gordon (b) (4) | 09 Aug 2020 14:04:58 |
| | (b) (4) | |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:25:19

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| User entered 'ug (ug)' | Tarin Gordon (b) (4) (b) (4) | 09 Aug 2020 14:04:58 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:25:19

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| User entered empty. | Tarin Gordon (b) (4) (b) (4) | 09 Aug 2020 14:04:58 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:25:19

[Frequency](#)

| Audit | User | Time (GMT) |
|---|----------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| | | |
| User entered 'once daily (QD)' reason for change: | Tarin Gordon (b) (4) | 09 Aug 2020 14:22:49 |
| Data Entry Error | (b) (4) | |
| User entered 'as needed (PRN)' | Tarin Gordon (b) (4) | 09 Aug 2020 14:04:58 |
| | (b) (4) | |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:25:19

If frequency is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| User entered empty. | Tarin Gordon (b) (4) (b) (4) | 09 Aug 2020 14:04:58 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:25:19

[Route of administration](#)

| Audit | User | Time (GMT) |
|---|----------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| | | |
| User closed query 'Per MM, route of administration is oral. Please review and update route of administration, as appropriate.' (Site from DM). | (b) (4), (b) (6) | 10 Sep 2020 15:14:55 |
| Query 'Per MM, route of administration is oral. Please review and update route of administration, as appropriate.' answered with 'Data updated' (Site from DM). | Tammy Kohn (b) (4) | 10 Sep 2020 13:29:36 |
| | (b) (4) | |
| User entered 'Nasal (NASAL)' reason for change: Data Entry Error | Tammy Kohn (b) (4) | 10 Sep 2020 13:29:28 |
| | (b) (4) | |
| User opened query 'Per MM, route of administration is oral. Please review and update route of administration, as appropriate.' (Site from DM). | (b) (4), (b) (6) | 04 Sep 2020 09:19:39 |
| | | |
| User entered 'Oral (ORAL)' | Tarin Gordon (b) (4) | 09 Aug 2020 14:04:58 |
| | (b) (4) | |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:25:19

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| User entered empty. | Tarin Gordon (b) (4) (b) (4) | 09 Aug 2020 14:04:58 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:25:19

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| | | |
| User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). | (b) (4), (b) (6) | 15 Aug 2020 17:40:51 |
| 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.' | Tarin Gordon (b) (4) | 09 Aug 2020 14:22:21 |
| answered with 'ONGOING' (Site from System). | (b) (4) | |
| 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 | 09 Aug 2020 14:04:58 |
| User entered 'UN UNK 2016' | Tarin Gordon (b) (4) | 09 Aug 2020 14:04:58 |
| | (b) (4) | |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:25:19

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| | | |
| User entered '0' | Tarin Gordon (b) (4) | 09 Aug 2020 14:04:58 |
| | (b) (4) | |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:25:19

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| User entered 'Yes (Y)' | Tarin Gordon (b) (4) (b) (4) | 09 Aug 2020 14:04:58 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:25:19

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| User entered empty. | Tarin Gordon (b) (4) (b) (4) | 09 Aug 2020 14:04:58 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:25:19

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| User entered 'No (N)' | Tarin Gordon (b) (4) (b) (4) | 09 Aug 2020 14:04:58 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:25:19

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered '1' | System | 09 Aug 2020 14:22:49 |
| User entered empty. | System | 09 Aug 2020 14:04:58 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:25:19

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered '1' | System | 09 Aug 2020 14:22:49 |
| User entered empty. | System | 09 Aug 2020 14:04:58 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:25:19

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 09 Aug 2020 14:22:49 |
| User entered empty. | System | 09 Aug 2020 14:04:58 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:25:19

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:40:55 |
| | | |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| | (b) (4) | |
| 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. | Coder Import (b) (4) | 06 Mar 2021 20:08:05 |
| | (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 Mar 2021 20:08:05 |
| | (b) (4) | |
| Data point term sent to Coder | System | 04 Mar 2021 13:23:55 |
| Coding entries removed. | Tammy Kohn (b) (4) | 04 Mar 2021 13:23:05 |
| | (b) (4) | |
| 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. | Coder Import (b) (4) | 02 Mar 2021 13:13:49 |
| | (b) (4) | |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 02 Mar 2021 13:13:49 |
| | (b) (4) | |
| Data point term sent to Coder | System | 02 Mar 2021 13:12:25 |
| Data point term sent to Coder | System | 22 Feb 2021 16:44:24 |
| Coding entries removed. | Tammy Kohn (b) (4) | 22 Feb 2021 16:44:04 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| | | |
| | | |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:25:19

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--|---|--|
| User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 21 Oct 2020 23:04:38 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 21 Oct 2020 23:04:38 |
| Data point term sent to Coder Coding entries removed. | System Tammy Kohn (b) (4) (b) (4) | 20 Oct 2020 13:44:13 20 Oct 2020 13:43:20 |
| User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 17 Sep 2020 19:00:44 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 17 Sep 2020 19:00:44 |
| Data point term sent to Coder User entered 'IBUPROFEN' | System Traci Hull (b) (4) (b) (4) | 17 Sep 2020 19:00:04 17 Sep 2020 18:59:47 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:25:19

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:40:55 |
| | | |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| | | |
| User entered 'No (N)' | Traci Hull (b) (4) | 17 Sep 2020 18:59:47 |
| | (b) (4) | |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:25:19

[Indication](#)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:40:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 17:34:54 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| User entered 'HEADACHE/MILD MUSCLE AND JOINT ACHES' reason for change: Data Entry Error | Tammy Kohn (b) (4) | 04 Mar 2021 13:23:05 |
| User closed query 'Per CDM re-query: Per previous query, there is no record of Headache for the recorded dates. Please review if dates need to be reconciled between CM and eDiary CRF pages and update accordingly else please review if the recorded indication "Headache" should be considered as unsolicited event per protocol. If yes, add AE as appropriate. ' (Site from DM). | (b) (4), (b) (6) | 03 Mar 2021 05:55:34 |
| Query 'Per CDM re-query: Per previous query, there is no record of Headache for the recorded dates. Please review if dates need to be reconciled between CM and eDiary CRF pages and update accordingly else please review if the recorded indication "Headache" should be considered as unsolicited event per protocol. If yes, add AE as appropriate. ' answered with 'NOT AN AE OR SAE AS THIS IS WITHIN THE 7 DAYS OF INJECTION' (Site from DM). | Tammy Kohn (b) (4) | 02 Mar 2021 13:12:20 |
| User entered 'MILD MUSCLE AND JOINT ACHES' reason for change: Data Entry Error | Tammy Kohn (b) (4) | 02 Mar 2021 13:11:49 |
| User closed query 'Per DM CLR: Please note that there is no AE or Dairy event that matches this Con med indication of HEADACHE during this time frame. Review if this should be recorded as an Adverse Event (unsolicited). Else, provide clarification if this will not be recorded on AE ecrf.' (Site from DM). | (b) (4), (b) (6) | 02 Mar 2021 10:11:00 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:25:19

[Indication](#)

| Audit | User | Time (GMT) |
|--|-------------------------------|----------------------|
| User opened query 'Per CDM re-query: Per previous query, there is no record of Headache for the recorded dates. Please review if dates need to be reconciled between CM and eDiary CRF pages and update accordingly else please review if the recorded indication "Headache" should be considered as unsolicited event per protocol. If yes, add AE as appropriate. ' (Site from DM). | (b) (4), (b) (6) | 02 Mar 2021 10:10:58 |
| User closed query ' Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the MILD MUSCLE AND JOINT ACHES are considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of MILD MUSCLE AND JOINT ACHES did not meet the AE reporting criteria' (Site from DM). | (b) (4), (b) (6) | 02 Mar 2021 05:24:03 |
| Query 'Per DM CLR: Please note that there is no AE or Dairy event that matches this Con med indication of HEADACHE during this time frame. Review if this should be recorded as an Adverse Event (unsolicited). Else, provide clarification if this will not be recorded on AE ecrf.' answered with 'NOT AN AE OR SAE AS THIS IS WITHIN THE 7 DAYS OF INJECTION' (Site from DM). | Tammy Kohn (b) (4) (b) (4) | 01 Mar 2021 19:26:51 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:25:19

[Indication](#)

| Audit | User | Time (GMT) |
|---|-------------------------------|----------------------|
| Query ' Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the MILD MUSCLE AND JOINT ACHES are considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of MILD MUSCLE AND JOINT ACHES did not meet the AE reporting criteria' answered with 'NOT AN AE OR SAE AS THIS IS WITHIN THE 7 DAYS OF INJECTION' (Site from DM). | Tammy Kohn (b) (4) (b) (4) | 01 Mar 2021 19:26:42 |
| User opened query 'Per DM CLR: Please note that there is no AE or Dairy event that matches this Con med indication of HEADACHE during this time frame. Review if this should be recorded as an Adverse Event (unsolicited). Else, provide clarification if this will not be recorded on AE ecrf.' (Site from DM). | (b) (4), (b) (6) | 01 Mar 2021 04:05:49 |
| Query 'Per DM CLR: Please note that there is no AE or Dairy event that matches this Con med indication of HEADACHE. Review if this should be recorded as an Adverse Event (unsolicited). Else, provide clarification if this will not be recorded on AE ecrf.' canceled (Site from DM). | (b) (4), (b) (6) | 01 Mar 2021 04:05:36 |
| User opened query 'Per DM CLR: Please note that there is no AE or Dairy event that matches this Con med indication of HEADACHE. Review if this should be recorded as an Adverse Event (unsolicited). Else, provide clarification if this will not be recorded on AE ecrf.' (Site from DM). | (b) (4), (b) (6) | 01 Mar 2021 04:04:54 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:25:19

[Indication](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| User opened query ' Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the MILD MUSCLE AND JOINT ACHES are considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of MILD MUSCLE AND JOINT ACHES did not meet the AE reporting criteria' (Site from DM). | (b) (4), (b) (6) | 01 Mar 2021 04:04:39 |
| Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the MILD MUSCLE AND JOINT ACHES is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of MILD MUSCLE AND JOINT ACHES did not meet the AE reporting criteria.' canceled (Site from DM). | (b) (4), (b) (6) | 01 Mar 2021 04:04:28 |
| User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the MILD MUSCLE AND JOINT ACHES is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of MILD MUSCLE AND JOINT ACHES did not meet the AE reporting criteria.' (Site from DM). | (b) (4), (b) (6) | 01 Mar 2021 04:04:20 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:25:19

[Indication](#)

| Audit | User | Time (GMT) |
|---|--------------------|----------------------|
| DataPoint Un-verified. | Tammy Kohn (b) (4) | 22 Feb 2021 16:44:04 |
| | (b) (4) | |
| User entered 'HEADACHE/MILD MUSCLE AND JOINT ACHES' reason for change: Data Entry Error | Tammy Kohn (b) (4) | 22 Feb 2021 16:44:04 |
| | (b) (4) | |
| User closed query 'Per DM CLR: Please update the indication to reflect the location of MUSCLE AND JOINT ACHES. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM). | (b) (4), (b) (6) | 08 Jan 2021 14:25:33 |
| | | |
| Query 'Per DM CLR: Please update the indication to reflect the location of MUSCLE AND JOINT ACHES. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' answered with 'NO AE OR SAE A PATIENT HAD MILD MUSCLE AND JOINT PAIN AFTER INJECTION' (Site from DM). | Tammy Kohn (b) (4) | 07 Jan 2021 21:32:10 |
| | (b) (4) | |
| User opened query 'Per DM CLR: Please update the indication to reflect the location of MUSCLE AND JOINT ACHES. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM). | (b) (4), (b) (6) | 07 Jan 2021 14:13:29 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| | | |
| | | |
| User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the MUSCLE AND JOINT ACHES is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, clarify.' (Site from DM). | (b) (4), (b) (6) | 21 Oct 2020 12:01:11 |
| | | |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:25:19

[Indication](#)

| Audit | User | Time (GMT) |
|---|--------------------|----------------------|
| Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the MUSCLE AND JOINT ACHES is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, clarify.' answered with 'DATA UPDATED NOT AN AE OR SAE OR MAAE' (Site from DM). | Tammy Kohn (b) (4) | 20 Oct 2020 13:43:33 |
| User entered 'MILD MUSCLE AND JOINT ACHES' reason for change: Data Entry Error | (b) (4) | 20 Oct 2020 13:43:20 |
| User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the MUSCLE AND JOINT ACHES is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, clarify.' (Site from DM). | (b) (4), (b) (6) | 20 Oct 2020 09:31:42 |
| User entered 'MUSCLE AND JOINT ACHES' | Traci Hull (b) (4) | 17 Sep 2020 18:59:47 |
| | (b) (4) | |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:25:19

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:40:55 |
| | | |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| | | |
| User entered '200' | Traci Hull (b) (4) | 17 Sep 2020 18:59:47 |
| | (b) (4) | |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:25:19

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:40:55 |
| | | |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| | | |
| User entered 'mg (mg)' | Traci Hull (b) (4) | 17 Sep 2020 18:59:47 |
| | (b) (4) | |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:25:19

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:40:55 |
| | | |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| | | |
| User entered empty. | Traci Hull (b) (4) | 17 Sep 2020 18:59:47 |
| | (b) (4) | |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:25:19

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:40:55 |
| | | |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| | | |
| User entered 'as needed (PRN)' | Traci Hull (b) (4) | 17 Sep 2020 18:59:47 |
| | (b) (4) | |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:25:19

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:40:55 |
| | | |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| | | |
| User entered empty. | Traci Hull (b) (4) | 17 Sep 2020 18:59:47 |
| | (b) (4) | |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:25:19

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:40:55 |
| | | |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| | | |
| User entered 'Oral (ORAL)' | Traci Hull (b) (4) | 17 Sep 2020 18:59:47 |
| | (b) (4) | |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:25:19

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:40:55 |
| | | |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| | | |
| User entered empty. | Traci Hull (b) (4) | 17 Sep 2020 18:59:47 |
| | (b) (4) | |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:25:19

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:40:55 |
| | | |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| | | |
| User entered '13 Sep 2020' | Traci Hull (b) (4) | 17 Sep 2020 18:59:47 |
| | (b) (4) | |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:25:19

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:40:55 |
| | | |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| | | |
| User entered '0' | Traci Hull (b) (4) | 17 Sep 2020 18:59:47 |
| | (b) (4) | |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:25:19

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:40:55 |
| | | |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| | | |
| User entered 'No (N)' | Traci Hull (b) (4) | 17 Sep 2020 18:59:47 |
| | (b) (4) | |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:25:19

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:40:55 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 17:38:39 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Un-verified. | Tammy Kohn (b) (4) | 04 Mar 2021 13:13:27 |
| User entered '15 Sep 2020' reason for change: Data Entry Error | Tammy Kohn (b) (4) | 04 Mar 2021 13:13:27 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| User entered '14 Sep 2020' | Traci Hull (b) (4) | 17 Sep 2020 18:59:47 |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:25:19

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:40:55 |
| | | |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| | | |
| User entered 'Yes (Y)' | Traci Hull (b) (4) | 17 Sep 2020 18:59:47 |
| | (b) (4) | |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:25:19

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:40:55 |
| | | |
| User entered empty. | System | 17 Sep 2020 18:59:47 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:25:19

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:40:55 |
| | | |
| User entered empty. | System | 17 Sep 2020 18:59:47 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:25:19

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:40:55 |
| | | |
| User entered empty. | System | 17 Sep 2020 18:59:47 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:25:19

Name of Medication

| Audit | User | Time (GMT) |
|---|---------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| | | |
| User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: LOW-CEILING DIURETICS, THIAZIDES, ATC: THIAZIDES, PLAIN, PRODUCT: HYDROCHLOROTHIAZIDE - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 26 Sep 2020 15:07:44 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 26 Sep 2020 15:07:44 |
| Data point term sent to Coder | System | 26 Sep 2020 15:06:21 |
| User entered 'HYDROCHLOROTHIAZIDE' | Tammy Kohn (b) (4) (b) (4) | 26 Sep 2020 15:05:53 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:25:19

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| | | |
| User entered 'No (N)' | Tammy Kohn (b) (4) | 26 Sep 2020 15:05:53 |
| | (b) (4) | |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:25:19

[Indication](#)

| Audit | User | Time (GMT) |
|-----------------------------|--------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| | | |
| User entered 'HYPERTENSION' | Tammy Kohn (b) (4) | 26 Sep 2020 15:05:53 |
| | (b) (4) | |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:25:19

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| User entered '12.5' | Tammy Kohn (b) (4) (b) (4) | 26 Sep 2020 15:05:53 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:25:19

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| User entered 'mg (mg)' | Tammy Kohn (b) (4) (b) (4) | 26 Sep 2020 15:05:53 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:25:19

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| | | |
| User entered empty. | Tammy Kohn (b) (4) | 26 Sep 2020 15:05:53 |
| | (b) (4) | |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:25:19

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|--------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| | | |
| User entered 'once daily (QD)' | Tammy Kohn (b) (4) | 26 Sep 2020 15:05:53 |
| | (b) (4) | |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:25:19

If frequency is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| User entered empty. | Tammy Kohn (b) (4) (b) (4) | 26 Sep 2020 15:05:53 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:25:19

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| | | |
| User entered 'Oral (ORAL)' | Tammy Kohn (b) (4) | 26 Sep 2020 15:05:53 |
| | (b) (4) | |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:25:19

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| | | |
| User entered empty. | Tammy Kohn (b) (4) | 26 Sep 2020 15:05:53 |
| | (b) (4) | |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|----------------------------|--------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| | | |
| User entered 'UN UNK 2000' | Tammy Kohn (b) (4) | 26 Sep 2020 15:05:53 |
| | (b) (4) | |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:25:19

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| User entered '0' | Tammy Kohn (b) (4) (b) (4) | 26 Sep 2020 15:05:53 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:25:19

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| User entered 'Yes (Y)' | Tammy Kohn (b) (4) (b) (4) | 26 Sep 2020 15:05:53 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:25:19

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|-------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| User entered empty. | Tammy Kohn (b) (4) (b) (4) | 26 Sep 2020 15:05:53 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:25:19

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| | | |
| User closed query 'Data is required. Please complete.' (Site from System). | System | 26 Sep 2020 15:05:59 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 26 Sep 2020 15:05:59 |
| User entered 'No (N)' reason for change: Data Entry Error | Tammy Kohn (b) (4) | 26 Sep 2020 15:05:59 |
| | (b) (4) | |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 26 Sep 2020 15:05:53 |
| User entered empty. | Tammy Kohn (b) (4) | 26 Sep 2020 15:05:53 |
| | (b) (4) | |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:25:19

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 26 Sep 2020 15:05:53 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:25:19

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 26 Sep 2020 15:05:53 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:25:19

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 26 Sep 2020 15:05:53 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:25:19

[Name of Medication](#)

| Audit | User | Time (GMT) |
|---|--------------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: THIRD-GENERATION CEPHALOSPORINS, PRODUCT: CEFTRIAXONE - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 13 Oct 2020 23:30:25 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 13 Oct 2020 23:30:25 |
| Data point term sent to Coder | System | 13 Oct 2020 22:17:43 |
| User entered 'CEFTRIAXONE' | Jennifer Molstead (b) (4) (b) (4) | 13 Oct 2020 22:16:53 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:25:19

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| User entered 'No (N)' | Jennifer Molstead (b) (4) (b) (4) | 13 Oct 2020 22:16:53 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:25:19

[Indication](#)

| Audit | User | Time (GMT) |
|-----------------------------|--------------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| User entered 'KIDNEY STONE' | Jennifer Molstead (b) (4) (b) (4) | 13 Oct 2020 22:16:53 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:25:19

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| User entered 'I' | Jennifer Molstead (b) (4) (b) (4) | 13 Oct 2020 22:16:53 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:25:19

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| User entered 'g (g)' | Jennifer Molstead (b) (4) (b) (4) | 13 Oct 2020 22:16:53 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:25:19

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| User entered empty. | Jennifer Molstead (b) (4) (b) (4) | 13 Oct 2020 22:16:53 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:25:19

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|--------------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| User entered 'once daily (QD)' | Jennifer Molstead (b) (4) (b) (4) | 13 Oct 2020 22:16:53 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:25:19

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| User entered empty. | Jennifer Molstead (b) (4) (b) (4) | 13 Oct 2020 22:16:53 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:25:19

[Route of administration](#)

| Audit | User | Time (GMT) |
|--|--------------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| User entered 'Intravenous (INTRAVENOUS)' | Jennifer Molstead (b) (4) (b) (4) | 13 Oct 2020 22:16:53 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:25:19

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| User entered empty. | Jennifer Molstead (b) (4) (b) (4) | 13 Oct 2020 22:16:53 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:25:19

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

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| User entered '23 Sep 2020' | Jennifer Molstead (b) (4) (b) (4) | 13 Oct 2020 22:16:53 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:25:19

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| User entered '0' | Jennifer Molstead (b) (4) (b) (4) | 13 Oct 2020 22:16:53 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:25:19

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---|--------------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' (Site from DM). | (b) (4) (b) (4), (b) (6) | 30 Nov 2020 13:56:27 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' answered with 'correct as is' (Site from DM). | Traci Hull (b) (4) (b) (4) | 17 Nov 2020 15:53:52 |
| User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' (Site from DM). | (b) (4), (b) (6) | 16 Nov 2020 07:47:53 |
| Query 'v' canceled (Site from DM). | (b) (4), (b) (6) | 16 Nov 2020 07:47:50 |
| User opened query 'v' (Site from DM). | (b) (4), (b) (6) | 16 Nov 2020 07:47:48 |
| User entered 'Yes (Y)' | Jennifer Molstead (b) (4) (b) (4) | 13 Oct 2020 22:16:53 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:25:19

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| User entered empty. | Jennifer Molstead (b) (4) (b) (4) | 13 Oct 2020 22:16:53 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:25:19

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| User entered 'No (N)' | Jennifer Molstead (b) (4) (b) (4) | 13 Oct 2020 22:16:53 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:25:19

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 13 Oct 2020 22:16:53 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:25:19

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 13 Oct 2020 22:16:53 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:25:19

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 13 Oct 2020 22:16:53 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:25:19

[Name of Medication](#)

| Audit | User | Time (GMT) |
|---|---------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:41:02 |
| | | |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| | | |
| User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: HEPARIN - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 14 Oct 2020 05:03:22 |
| | (b) (4) | |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 14 Oct 2020 05:03:22 |
| | (b) (4) | |
| Data point term sent to Coder | System | 13 Oct 2020 22:18:43 |
| User entered 'HEPARIN' | Jennifer Molstead (b) (4) | 13 Oct 2020 22:18:34 |
| | (b) (4) | |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:25:19

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|--|---------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:41:02 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| User closed query 'Per DM CLR: Prophylaxis = Yes. Please review if the response should be updated to 'No' as there is an AE recorded that matches this medication and used within the same timeframe. If yes, please update response as appropriate. ' (Site from DM). | (b) (4), (b) (6) | 23 Nov 2020 06:24:27 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| Query 'Per DM CLR: Prophylaxis = Yes. Please review if the response should be updated to 'No' as there is an AE recorded that matches this medication and used within the same timeframe. If yes, please update response as appropriate. ' answered with 'updated' (Site from DM). | Traci Hull (b) (4) | 17 Nov 2020 15:54:27 |
| User entered 'No (N)' reason for change: Per Query Resolution | Traci Hull (b) (4) | 17 Nov 2020 15:54:19 |
| User opened query 'Per DM CLR: Prophylaxis = Yes. Please review if the response should be updated to 'No' as there is an AE recorded that matches this medication and used within the same timeframe. If yes, please update response as appropriate. ' (Site from DM). | (b) (4), (b) (6) | 16 Nov 2020 07:49:18 |
| User entered 'Yes (Y)' | Jennifer Molstead (b) (4) | 13 Oct 2020 22:18:34 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:25:19

[Indication](#)

| Audit | User | Time (GMT) |
|-----------------------------|---------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:41:02 |
| | | |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| | | |
| | | |
| User entered 'KIDNEY STONE' | Jennifer Molstead (b) (4) | 13 Oct 2020 22:18:34 |
| | (b) (4) | |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:25:19

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:41:02 |
| | | |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| | | |
| | | |
| User entered '5000' | Jennifer Molstead (b) (4) | 13 Oct 2020 22:18:34 |
| | (b) (4) | |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:25:19

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:41:02 |
| | | |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| | | |
| | | |
| User entered 'IU (IU)' | Jennifer Molstead (b) (4) | 13 Oct 2020 22:18:34 |
| | (b) (4) | |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:25:19

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|---------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:41:02 |
| | | |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| | | |
| | | |
| User entered empty. | Jennifer Molstead (b) (4) | 13 Oct 2020 22:18:34 |
| | (b) (4) | |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:25:19

[Frequency](#)

| Audit | User | Time (GMT) |
|----------------------------------|---------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:41:02 |
| | | |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| | | |
| | | |
| User entered 'twice daily (BID)' | Jennifer Molstead (b) (4) | 13 Oct 2020 22:18:34 |
| | (b) (4) | |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:25:19

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:41:02 |
| | | |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| | | |
| | | |
| User entered empty. | Jennifer Molstead (b) (4) | 13 Oct 2020 22:18:34 |
| | (b) (4) | |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:25:19

[Route of administration](#)

| Audit | User | Time (GMT) |
|--|---------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:41:02 |
| | | |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| | | |
| | | |
| User entered 'Subcutaneous (SUBCUTANEOUS)' | Jennifer Molstead (b) (4) | 13 Oct 2020 22:18:34 |
| | (b) (4) | |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:25:19

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|---------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:41:02 |
| | | |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| | | |
| | | |
| User entered empty. | Jennifer Molstead (b) (4) | 13 Oct 2020 22:18:34 |
| | (b) (4) | |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:25:19

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:41:02 |
| | | |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| | | |
| | | |
| User entered '22 Sep 2020' | Jennifer Molstead (b) (4) | 13 Oct 2020 22:18:34 |
| | (b) (4) | |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:25:19

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:41:02 |
| | | |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| | | |
| | | |
| User entered '0' | Jennifer Molstead (b) (4) | 13 Oct 2020 22:18:34 |
| | (b) (4) | |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:25:19

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:41:02 |
| | | |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| | | |
| | | |
| User entered 'No (N)' | Jennifer Molstead (b) (4) | 13 Oct 2020 22:18:34 |
| | (b) (4) | |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:25:19

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:41:02 |
| | | |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| | | |
| | | |
| User entered '23 Sep 2020' | Jennifer Molstead (b) (4) | 13 Oct 2020 22:18:34 |
| | (b) (4) | |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:25:19

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:41:02 |
| | | |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| | | |
| | | |
| User entered 'No (N)' | Jennifer Molstead (b) (4) | 13 Oct 2020 22:18:34 |
| | (b) (4) | |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:25:19

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:41:02 |
| | | |
| User entered '2' | System | 13 Oct 2020 22:18:34 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:25:19

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:41:02 |
| | | |
| User entered '1' | System | 13 Oct 2020 22:18:34 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:25:19

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:41:02 |
| | | |
| User entered '804 (804)' | System | 13 Oct 2020 22:18:34 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:25:19

[Name of Medication](#)

| Audit | User | Time (GMT) |
|---|---------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:41:13 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: ACETIC ACID DERIVATIVES AND RELATED SUBSTANCES, PRODUCT: KETOROLAC - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 14 Oct 2020 05:51:23 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 14 Oct 2020 05:51:23 |
| Data point term sent to Coder | System | 13 Oct 2020 22:19:46 |
| User entered 'KETOROLAC' | Jennifer Molstead (b) (4) | 13 Oct 2020 22:19:36 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:25:19

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:41:13 |
| | | |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| | | |
| | | |
| User entered 'No (N)' | Jennifer Molstead (b) (4) | 13 Oct 2020 22:19:36 |
| | (b) (4) | |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:25:19

[Indication](#)

| Audit | User | Time (GMT) |
|-----------------------------|---------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:41:13 |
| | | |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| | | |
| | | |
| User entered 'KIDNEY STONE' | Jennifer Molstead (b) (4) | 13 Oct 2020 22:19:36 |
| | (b) (4) | |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:25:19

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:41:13 |
| | | |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| | | |
| | | |
| User entered '30' | Jennifer Molstead (b) (4) | 13 Oct 2020 22:19:36 |
| | (b) (4) | |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:25:19

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:41:13 |
| | | |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| | | |
| | | |
| User entered 'mg (mg)' | Jennifer Molstead (b) (4) | 13 Oct 2020 22:19:36 |
| | (b) (4) | |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:25:19

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|---------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:41:13 |
| | | |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| | | |
| | | |
| User entered empty. | Jennifer Molstead (b) (4) | 13 Oct 2020 22:19:36 |
| | (b) (4) | |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:25:19

[Frequency](#)

| Audit | User | Time (GMT) |
|---------------------------------------|---------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:41:13 |
| | | |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| | | |
| | | |
| User entered 'four times daily (QID)' | Jennifer Molstead (b) (4) | 13 Oct 2020 22:19:36 |
| | (b) (4) | |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:25:19

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:41:13 |
| | | |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| | | |
| | | |
| User entered empty. | Jennifer Molstead (b) (4) | 13 Oct 2020 22:19:36 |
| | (b) (4) | |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:25:19

[Route of administration](#)

| Audit | User | Time (GMT) |
|--|---------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:41:13 |
| | | |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| | | |
| User entered 'Intravenous (INTRAVENOUS)' | Jennifer Molstead (b) (4) | 13 Oct 2020 22:19:36 |
| | (b) (4) | |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:25:19

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|---------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:41:13 |
| | | |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| | | |
| User entered empty. | Jennifer Molstead (b) (4) | 13 Oct 2020 22:19:36 |
| | (b) (4) | |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:25:19

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:41:13 |
| | | |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| | | |
| | | |
| User entered '22 Sep 2020' | Jennifer Molstead (b) (4) | 13 Oct 2020 22:19:36 |
| | (b) (4) | |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:25:19

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:41:13 |
| | | |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| | | |
| | | |
| User entered '0' | Jennifer Molstead (b) (4) | 13 Oct 2020 22:19:36 |
| | (b) (4) | |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:25:19

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:41:13 |
| | | |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| | | |
| | | |
| User entered 'No (N)' | Jennifer Molstead (b) (4) | 13 Oct 2020 22:19:36 |
| | (b) (4) | |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:25:19

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:41:13 |
| | | |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| | | |
| | | |
| User entered '23 Sep 2020' | Jennifer Molstead (b) (4) | 13 Oct 2020 22:19:36 |
| | (b) (4) | |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:25:19

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:41:13 |
| | | |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| | | |
| | | |
| User entered 'No (N)' | Jennifer Molstead (b) (4) | 13 Oct 2020 22:19:36 |
| | (b) (4) | |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:25:19

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:41:13 |
| | | |
| User entered '4' | System | 13 Oct 2020 22:19:36 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:25:19

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:41:13 |
| | | |
| User entered '1' | System | 13 Oct 2020 22:19:36 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:25:19

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:41:13 |
| | | |
| User entered '804 (804)' | System | 13 Oct 2020 22:19:36 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:25:19

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--|--------------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY, ATC: ALPHA-ADRENORECEPTOR ANTAGONISTS, PRODUCT: TAMSULOSIN - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 14 Oct 2020 05:17:30 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 14 Oct 2020 05:17:30 |
| Data point term sent to Coder | System | 13 Oct 2020 22:20:47 |
| User entered 'TAMSULOSIN' | Jennifer Molstead (b) (4) (b) (4) | 13 Oct 2020 22:20:17 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:25:19

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| User entered 'No (N)' | Jennifer Molstead (b) (4) (b) (4) | 13 Oct 2020 22:20:17 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:25:19

[Indication](#)

| Audit | User | Time (GMT) |
|-----------------------------|--------------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| User entered 'KIDNEY STONE' | Jennifer Molstead (b) (4) (b) (4) | 13 Oct 2020 22:20:17 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:25:19

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| User entered '0.4' | Jennifer Molstead (b) (4) (b) (4) | 13 Oct 2020 22:20:17 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:25:19

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| User entered 'mg (mg)' | Jennifer Molstead (b) (4) (b) (4) | 13 Oct 2020 22:20:17 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:25:19

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| User entered empty. | Jennifer Molstead (b) (4) (b) (4) | 13 Oct 2020 22:20:17 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:25:19

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|--------------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| User entered 'once daily (QD)' | Jennifer Molstead (b) (4) (b) (4) | 13 Oct 2020 22:20:17 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:25:19

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| User entered empty. | Jennifer Molstead (b) (4) (b) (4) | 13 Oct 2020 22:20:17 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:25:19

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| User entered 'Oral (ORAL)' | Jennifer Molstead (b) (4) (b) (4) | 13 Oct 2020 22:20:17 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:25:19

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| User entered empty. | Jennifer Molstead (b) (4) (b) (4) | 13 Oct 2020 22:20:17 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:25:19

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|---------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| | (b) (4) | |
| User closed query 'Per source, the start date was 23-SEP-2020.' (Site from CRA). | (b) (4), (b) (6) | 20 Apr 2021 15:17:33 |
| | | |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Apr 2021 15:17:30 |
| | | |
| Query 'Per source, the start date was 23-SEP-2020.' answered with 'UPDATED' (Site from CRA). | Tammy Kohn (b) (4) | 17 Apr 2021 16:14:50 |
| | (b) (4) | |
| DataPoint Un-verified. | Tammy Kohn (b) (4) | 17 Apr 2021 16:12:08 |
| | (b) (4) | |
| Signature has been broken. | Tammy Kohn (b) (4) | 17 Apr 2021 16:12:08 |
| | (b) (4) | |
| User entered '23 Sep 2020' reason for change: Data Entry Error | Tammy Kohn (b) (4) | 17 Apr 2021 16:12:08 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 17:37:00 |
| | | |
| User opened query 'Per source, the start date was 23-SEP-2020.' (Site from CRA). | (b) (4), (b) (6) | 16 Apr 2021 17:36:58 |
| | | |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| | (b) (4) | |
| DataPoint Un-verified. | Tammy Kohn (b) (4) | 03 Dec 2020 13:19:20 |
| | (b) (4) | |
| User entered '22 Sep 2020' reason for change: Data Entry Error | Tammy Kohn (b) (4) | 03 Dec 2020 13:19:20 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| | | |
| | | |
| User entered '23 Sep 2020' | Jennifer Molstead (b) (4) | 13 Oct 2020 22:20:17 |
| | (b) (4) | |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:25:19

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| User entered '0' | Jennifer Molstead (b) (4) (b) (4) | 13 Oct 2020 22:20:17 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:25:19

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---|-------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 15:17:35 |
| DataPoint Un-verified. | Tammy Kohn (b) (4) | 17 Apr 2021 16:14:43 |
| Signature has been broken. | (b) (4) Tammy Kohn (b) (4) | 17 Apr 2021 16:14:43 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | (b) (4) Tammy Kohn (b) (4) | 17 Apr 2021 16:14:43 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 17:37:58 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| User closed query 'Per CDM query: Per previous query, please provide clarification for the continued use of this medication.' (Site from DM). | (b) (4) (b) (4), (b) (6) | 04 Dec 2020 06:41:18 |
| Query 'Per CDM query: Per previous query, please provide clarification for the continued use of this medication.' answered with 'UPDATED INFORMATION' (Site from DM). | Tammy Kohn (b) (4) | 03 Dec 2020 13:19:39 |
| DataPoint Un-verified. | (b) (4) Tammy Kohn (b) (4) | 03 Dec 2020 13:19:20 |
| User entered 'No (N)' reason for change: Data Entry Error | (b) (4) Tammy Kohn (b) (4) | 03 Dec 2020 13:19:20 |
| User opened query 'Per CDM query: Per previous query, please provide clarification for the continued use of this medication.' (Site from DM). | (b) (4), (b) (6) | 03 Dec 2020 11:47:00 |
| User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM). | (b) (4), (b) (6) | 03 Dec 2020 11:47:00 |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:25:19

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---|--------------------------------------|----------------------|
| Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' answered with 'correct as is' (Site from DM). | Traci Hull (b) (4) (b) (4) | 17 Nov 2020 15:54:59 |
| User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' (Site from DM). | (b) (4), (b) (6) (b) (4) | 16 Nov 2020 07:52:27 |
| User entered 'Yes (Y)' | Jennifer Molstead (b) (4) (b) (4) | 13 Oct 2020 22:20:17 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:25:19

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|---------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Apr 2021 15:17:38 |
| | | |
| User closed query 'Per source, end date is "ongoing". Please review and update appropriately.' (Site from CRA). | (b) (4), (b) (6) | 20 Apr 2021 15:17:27 |
| | | |
| Query 'Per source, end date is "ongoing". Please review and update appropriately.' answered with 'UPDATED' (Site from CRA). | Tammy Kohn (b) (4) | 17 Apr 2021 16:14:55 |
| | (b) (4) | |
| DataPoint Un-verified. | Tammy Kohn (b) (4) | 17 Apr 2021 16:14:43 |
| | (b) (4) | |
| Signature has been broken. | Tammy Kohn (b) (4) | 17 Apr 2021 16:14:43 |
| | (b) (4) | |
| User entered empty; reason for change Data Entry Error | Tammy Kohn (b) (4) | 17 Apr 2021 16:14:43 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 17:38:06 |
| | | |
| User opened query 'Per source, end date is "ongoing". Please review and update appropriately.' (Site from CRA). | (b) (4), (b) (6) | 16 Apr 2021 17:38:04 |
| | | |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| | (b) (4) | |
| DataPoint Un-verified. | Tammy Kohn (b) (4) | 03 Dec 2020 13:19:20 |
| | (b) (4) | |
| User entered '23 Sep 2020' reason for change: Data Entry Error | Tammy Kohn (b) (4) | 03 Dec 2020 13:19:20 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| | | |
| | | |
| User entered empty. | Jennifer Molstead (b) (4) | 13 Oct 2020 22:20:17 |
| | (b) (4) | |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:25:19

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Nov 2020 20:40:36 |
| User entered 'No (N)' | Jennifer Molstead (b) (4) (b) (4) | 13 Oct 2020 22:20:17 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:25:19

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 13 Oct 2020 22:20:17 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:25:19

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 13 Oct 2020 22:20:17 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:25:19

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 13 Oct 2020 22:20:17 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:25:19

Name of Medication

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:41:18 |
| User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: SODIUM CHLORIDE, PRODUCTSYNONYM: SODIUM CHLORIDE 0.9% - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 18 Apr 2021 16:19:56 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 18 Apr 2021 16:19:56 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 17:38:39 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTION ADDITIVES, ATC: ELECTROLYTE SOLUTIONS, PRODUCT: SODIUM CHLORIDE, PRODUCTSYNONYM: SODIUM CHLORIDE 0.9% - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 15 Mar 2021 15:17:57 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 15 Mar 2021 15:17:57 |
| Data point term sent to Coder | System | 09 Mar 2021 14:03:29 |
| Coding entries removed. | Tammy Kohn (b) (4) | 09 Mar 2021 14:02:41 |
| User entered 'SODIUM CHLORIDE 0.9%' reason for change: Data Entry Error | Tammy Kohn (b) (4) | 09 Mar 2021 14:02:41 |
| User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: SODIUM CHLORIDE - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 02 Dec 2020 10:31:59 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:25:19

[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) | 02 Dec 2020 10:31:59 |
| Data point term sent to Coder | System | 01 Dec 2020 17:25:26 |
| User entered 'SODIUM CHLORIDE' | Tammy Kohn (b) (4) | 01 Dec 2020 17:25:12 |
| DataPoint activated with code reason code Data required. | (b) (4) | |
| | Tammy Kohn (b) (4) | 01 Dec 2020 17:23:37 |
| | (b) (4) | |
| DataPoint inactivated with code reason code Data not required. | Tammy Kohn (b) (4) | 22 Oct 2020 20:05:58 |
| | (b) (4) | |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:25:19

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:41:18 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 17:38:39 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| User entered 'No (N)' | Tammy Kohn (b) (4) | 01 Dec 2020 17:25:12 |
| DataPoint activated with code reason code Data required. | Tammy Kohn (b) (4) | 01 Dec 2020 17:23:37 |
| DataPoint inactivated with code reason code Data not required. | Tammy Kohn (b) (4) | 22 Oct 2020 20:05:58 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:25:19

[Indication](#)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:41:18 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 17:38:39 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| User entered 'KIDNEY STONES' | Tammy Kohn (b) (4) | 01 Dec 2020 17:25:12 |
| DataPoint activated with code reason code Data required. | Tammy Kohn (b) (4) | 01 Dec 2020 17:23:37 |
| DataPoint inactivated with code reason code Data not required. | Tammy Kohn (b) (4) | 22 Oct 2020 20:05:58 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:25:19

[Dose per administration](#)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:41:18 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 17:38:39 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| User closed query 'Per DM CLR: Note, 0.9% is a concentration, please update medication name to include this concentration and update dose and dose unit with the actual dose administered (eg, 1000ml, 500ml, etc). Update as appropriate. ' (Site from DM). | (b) (4), (b) (6) | 10 Mar 2021 05:17:06 |
| Query 'Per DM CLR: Note, 0.9% is a concentration, please update medication name to include this concentration and update dose and dose unit with the actual dose administered (eg, 1000ml, 500ml, etc). Update as appropriate. ' answered with '100 ML PER HOUR' (Site from DM). | Tammy Kohn (b) (4) | 09 Mar 2021 14:03:13 |
| User entered '100' reason for change: Data Entry Error | Tammy Kohn (b) (4) | 09 Mar 2021 14:03:06 |
| User entered '500' reason for change: Data Entry Error | Tammy Kohn (b) (4) | 09 Mar 2021 14:02:41 |
| User opened query 'Per DM CLR: Note, 0.9% is a concentration, please update medication name to include this concentration and update dose and dose unit with the actual dose administered (eg, 1000ml, 500ml, etc). Update as appropriate. ' (Site from DM). | (b) (4), (b) (6) | 09 Mar 2021 08:19:34 |
| User entered '0.9%' | Tammy Kohn (b) (4) | 01 Dec 2020 17:25:12 |
| DataPoint activated with code reason code Data required. | Tammy Kohn (b) (4) | 01 Dec 2020 17:23:37 |
| DataPoint inactivated with code reason code Data not required. | Tammy Kohn (b) (4) | 22 Oct 2020 20:05:58 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:25:19

[Dose unit](#)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:41:18 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 17:38:39 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| User entered 'mL (mL)' | Tammy Kohn (b) (4) | 01 Dec 2020 17:25:12 |
| DataPoint activated with code reason code Data required. | Tammy Kohn (b) (4) | 01 Dec 2020 17:23:37 |
| DataPoint inactivated with code reason code Data not required. | Tammy Kohn (b) (4) | 22 Oct 2020 20:05:58 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:25:19

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:41:18 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 17:38:39 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| User entered empty. | Tammy Kohn (b) (4) | 01 Dec 2020 17:25:12 |
| DataPoint activated with code reason code Data required. | Tammy Kohn (b) (4) | 01 Dec 2020 17:23:37 |
| DataPoint inactivated with code reason code Data not required. | Tammy Kohn (b) (4) | 22 Oct 2020 20:05:58 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:25:19

[Frequency](#)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:41:18 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 17:38:39 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| User entered 'other (OTHER)' | Tammy Kohn (b) (4) | 01 Dec 2020 17:25:12 |
| DataPoint activated with code reason code Data required. | Tammy Kohn (b) (4) | 01 Dec 2020 17:23:37 |
| DataPoint inactivated with code reason code Data not required. | Tammy Kohn (b) (4) | 22 Oct 2020 20:05:58 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:25:19

If frequency is Other, specify

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:41:18 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 17:38:39 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| User entered '100 ML PER HOUR' | Tammy Kohn (b) (4) | 01 Dec 2020 17:25:12 |
| DataPoint activated with code reason code Data required. | Tammy Kohn (b) (4) | 01 Dec 2020 17:23:37 |
| DataPoint inactivated with code reason code Data not required. | Tammy Kohn (b) (4) | 22 Oct 2020 20:05:58 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:25:19

[Route of administration](#)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:41:18 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 17:38:39 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| User entered 'Intravenous Drip (INTRAVENOUS DRIP)' | Tammy Kohn (b) (4) | 01 Dec 2020 17:25:12 |
| DataPoint activated with code reason code Data required. | Tammy Kohn (b) (4) | 01 Dec 2020 17:23:37 |
| DataPoint inactivated with code reason code Data not required. | Tammy Kohn (b) (4) | 22 Oct 2020 20:05:58 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:25:19

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:41:18 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 17:38:39 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| User entered empty. | Tammy Kohn (b) (4) | 01 Dec 2020 17:25:12 |
| DataPoint activated with code reason code Data required. | Tammy Kohn (b) (4) | 01 Dec 2020 17:23:37 |
| DataPoint inactivated with code reason code Data not required. | Tammy Kohn (b) (4) | 22 Oct 2020 20:05:58 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:25:19

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:41:18 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 17:38:39 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| User entered '22 Sep 2020' | Tammy Kohn (b) (4) | 01 Dec 2020 17:25:12 |
| DataPoint activated with code reason code Data required. | Tammy Kohn (b) (4) | 01 Dec 2020 17:23:37 |
| DataPoint inactivated with code reason code Data not required. | Tammy Kohn (b) (4) | 22 Oct 2020 20:05:58 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:25:19

Start date completely unknown

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:41:18 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 17:38:39 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| User entered '0' | Tammy Kohn (b) (4) | 01 Dec 2020 17:25:12 |
| DataPoint activated with code reason code Data required. | Tammy Kohn (b) (4) | 01 Dec 2020 17:23:37 |
| DataPoint inactivated with code reason code Data not required. | Tammy Kohn (b) (4) | 22 Oct 2020 20:05:58 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:25:19

[Ongoing?](#)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:41:18 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 17:38:39 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| User entered 'No (N)' | Tammy Kohn (b) (4) | 01 Dec 2020 17:25:12 |
| DataPoint activated with code reason code Data required. | Tammy Kohn (b) (4) | 01 Dec 2020 17:23:37 |
| DataPoint inactivated with code reason code Data not required. | Tammy Kohn (b) (4) | 22 Oct 2020 20:05:58 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:25:19

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:41:18 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 17:38:39 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| User entered '23 Sep 2020' | Tammy Kohn (b) (4) | 01 Dec 2020 17:25:12 |
| DataPoint activated with code reason code Data required. | Tammy Kohn (b) (4) | 01 Dec 2020 17:23:37 |
| DataPoint inactivated with code reason code Data not required. | Tammy Kohn (b) (4) | 22 Oct 2020 20:05:58 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:25:19

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:41:18 |
| DataPoint Verified. | (b) (4), (b) (6) | 16 Apr 2021 17:38:39 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| User closed query 'Per DM CLR: Please note, 'Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body). Please review and update eCRF. Otherwise clarify. Per DM CLR: Please review the dosage as this is not the expected dosage for this medication. Please review and either correct dosage or provide explanation for alternate dosage of this medication. Please update eCRF as appropriate.' (Site from DM). Query 'Per DM CLR: Please note, 'Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body). Please review and update eCRF. Otherwise clarify. Per DM CLR: Please review the dosage as this is not the expected dosage for this medication. Please review and either correct dosage or provide explanation for alternate dosage of this medication. Please update eCRF as appropriate.' answered with 'This medication was take for Kidney stones per the AE.' (Site from DM). | (b) (4), (b) (6) | 28 Jan 2021 04:19:02 |
| User entered 'No (N)' reason for change: Data Entry Error | Tammy Kohn (b) (4) | 27 Jan 2021 12:40:10 |
| | (b) (4) | |
| | Tammy Kohn (b) (4) | 27 Jan 2021 12:39:46 |
| | (b) (4) | |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:25:19

Was this medication taken for solicited event?

| Audit | User | Time (GMT) |
|--|--|--|
| User opened query 'Per DM CLR: Please note, 'Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body). Please review and update eCRF. Otherwise clarify. Per DM CLR: Please review the dosage as this is not the expected dosage for this medication. Please review and either correct dosage or provide explanation for alternate dosage of this medication. Please update eCRF as appropriate.' (Site from DM). User entered 'Yes (Y)' | (b) (4), (b) (6) Tammy Kohn (b) (4) | 27 Jan 2021 01:56:15 01 Dec 2020 17:25:12 |
| DataPoint activated with code reason code Data required. | Tammy Kohn (b) (4) | 01 Dec 2020 17:23:37 |
| DataPoint inactivated with code reason code Data not required. | Tammy Kohn (b) (4) | 22 Oct 2020 20:05:58 |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:25:19

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:41:18 |
| | | |
| User entered empty. | System | 01 Dec 2020 17:25:12 |
| DataPoint activated with code reason code Data required. | Tammy Kohn (b) (4) | 01 Dec 2020 17:23:37 |
| | (b) (4) | |
| DataPoint inactivated with code reason code Data not required. | Tammy Kohn (b) (4) | 22 Oct 2020 20:05:58 |
| | (b) (4) | |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:25:19

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:41:18 |
| | | |
| User entered empty. | System | 01 Dec 2020 17:25:12 |
| DataPoint activated with code reason code Data required. | Tammy Kohn (b) (4) | 01 Dec 2020 17:23:37 |
| | (b) (4) | |
| DataPoint inactivated with code reason code Data not required. | Tammy Kohn (b) (4) | 22 Oct 2020 20:05:58 |
| | (b) (4) | |

US3402284

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:25:19

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--|--------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:41:18 |
| | | |
| User entered empty. | System | 01 Dec 2020 17:25:12 |
| DataPoint activated with code reason code Data required. | Tammy Kohn (b) (4) | 01 Dec 2020 17:23:37 |
| | (b) (4) | |
| DataPoint inactivated with code reason code Data not required. | Tammy Kohn (b) (4) | 22 Oct 2020 20:05:58 |
| | (b) (4) | |

US3402284

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 17:25:19

[Were any concomitant procedures performed?](#)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 06:32:45 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Nov 2020 20:40:51 |
| User entered 'Yes (Y)' reason for change: New Information | Jennifer Molstead (b) (4) | 24 Sep 2020 20:37:59 |
| User entered 'No (N)' | Traci Hull (b) (4) | 08 Aug 2020 20:43:14 |

US3402284

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:25:19

Procedure/Surgery date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 24 Nov 2020 15:32:51 |
| | | |
| User entered '22 Sep 2020' | Jennifer Molstead (b) (4) | 24 Sep 2020 20:38:56 |
| | (b) (4) | |

US3402284

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:25:19

[Procedure/Surgery](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 15:32:51 |
| User entered 'Lithotripsy' | Jennifer Molstead (b) (4) (b) (4) | 24 Sep 2020 20:38:56 |

US3402284

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:25:19

[Indication](#)

| Audit | User | Time (GMT) |
|-----------------------------------|--------------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 15:32:51 |
| User entered 'Adverse Event (AE)' | Jennifer Molstead (b) (4) (b) (4) | 24 Sep 2020 20:38:56 |

US3402284

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:25:19

If indication is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 15:32:51 |
| User entered empty. | Jennifer Molstead (b) (4) (b) (4) | 24 Sep 2020 20:38:56 |

US3402284

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:25:19

Procedure/Surgery date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 08:31:17 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 15:32:51 |
| User entered '22 Sep 2020' | Jennifer Molstead (b) (4) (b) (4) | 29 Oct 2020 21:41:54 |

US3402284

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:25:19

[Procedure/Surgery](#)

| Audit | User | Time (GMT) |
|---|--------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 08:31:17 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 15:32:51 |
| User entered 'CT OF ABDOMEN AND PELVIS' reason for change: New Information | Jennifer Molstead (b) (4) (b) (4) | 29 Oct 2020 21:43:02 |
| User entered 'Ultrasound of Abdomen and Pelvis' | Jennifer Molstead (b) (4) (b) (4) | 29 Oct 2020 21:41:54 |

US3402284

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:25:19

[Indication](#)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 08:31:17 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 15:32:51 |
| User entered 'Adverse Event (AE)' reason for change: Per Query Resolution | Jennifer Molstead (b) (4) | 29 Oct 2020 21:44:20 |
| User closed query 'Indication is not Other, however specify has been provided. Please correct.' (Site from System). | (b) (4) | |
| | System | 29 Oct 2020 21:43:02 |
| User entered 'Other (OTHER)' reason for change: Per Query Resolution | Jennifer Molstead (b) (4) | 29 Oct 2020 21:43:02 |
| | (b) (4) | |
| User opened query 'Indication is not Other, however specify has been provided. Please correct.' (Site from System). | System | 29 Oct 2020 21:41:54 |
| User entered 'Adverse Event (AE)' | Jennifer Molstead (b) (4) | 29 Oct 2020 21:41:54 |
| | (b) (4) | |

US3402284

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:25:19

If indication is Other, specify

| Audit | User | Time (GMT) |
|--|--------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 08:31:17 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 15:32:51 |
| User entered empty; reason for change Data Entry Error | Jennifer Molstead (b) (4) | 29 Oct 2020 21:44:20 |
| User entered 'Positive for Kidney Stones' | (b) (4) Jennifer Molstead (b) (4) | 29 Oct 2020 21:41:54 |

US3402284

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:25:19

Procedure/Surgery date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 08:31:18 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 15:32:51 |
| User entered '22 Sep 2020' | Jennifer Molstead (b) (4) (b) (4) | 29 Oct 2020 21:43:52 |

US3402284

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:25:19

[Procedure/Surgery](#)

| Audit | User | Time (GMT) |
|-------------------------------------|--------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 08:31:18 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 15:32:51 |
| User entered 'Complete Blood Count' | Jennifer Molstead (b) (4) (b) (4) | 29 Oct 2020 21:43:52 |

US3402284

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:25:19

[Indication](#)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 08:31:18 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 15:32:51 |
| User closed query 'Indication is not Other, however specify has been provided. Please correct.' (Site from System). | System | 29 Oct 2020 21:44:08 |
| User entered 'Adverse Event (AE)' reason for change: Data Entry Error | Jennifer Molstead (b) (4) | 29 Oct 2020 21:44:08 |
| User opened query 'Indication is not Other, however specify has been provided. Please correct.' (Site from System). | System | 29 Oct 2020 21:43:52 |
| User entered 'Diagnostic (DIAGNOSTIC)' | Jennifer Molstead (b) (4) | 29 Oct 2020 21:43:52 |

US3402284

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:25:19

If indication is Other, specify

| Audit | User | Time (GMT) |
|--|--------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 08:31:18 |
| User signature succeeded. | Frank Eder (b) (4) | 08 Apr 2021 23:35:52 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 15:32:51 |
| User entered empty; reason for change Data Entry Error | Jennifer Molstead (b) (4) | 29 Oct 2020 21:44:08 |
| User entered 'Elevated White count' | (b) (4) Jennifer Molstead (b) (4) | 29 Oct 2020 21:43:52 |

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:25:19

[SAEID](#)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 15:41:17 |
| Reviewed for Safety. | (b) (4), (b) (6) | 25 Sep 2020 15:16:58 |
| User entered 'USA-US059-2020-MRNA-1273-P301000004' | System | 25 Sep 2020 15:16:36 |

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:25:19

Serious

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 15:41:17 |
| Reviewed for Safety. | (b) (4), (b) (6) | 25 Sep 2020 15:16:58 |
| User entered 'Yes (Y)' | System | 25 Sep 2020 15:16:36 |

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:25:19

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 15:41:17 |
| Reviewed for Safety. | (b) (4), (b) (6) | 25 Sep 2020 15:16:58 |
| User entered 'No (N)' | System | 25 Sep 2020 15:16:36 |

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:25:19

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 15:41:17 |
| Reviewed for Safety. | (b) (4), (b) (6) | 25 Sep 2020 15:16:58 |
| User entered 'No (N)' | System | 25 Sep 2020 15:16:36 |

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:25:19

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 15:41:17 |
| Reviewed for Safety. | (b) (4), (b) (6) | 25 Sep 2020 15:16:58 |
| User entered 'Yes (Y)' | System | 25 Sep 2020 15:16:36 |

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:25:19

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 15:41:17 |
| Reviewed for Safety. | (b) (4), (b) (6) | 25 Sep 2020 15:16:58 |
| User entered 'No (N)' | System | 25 Sep 2020 15:16:36 |

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:25:19

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 15:41:17 |
| Reviewed for Safety. | (b) (4), (b) (6) | 25 Sep 2020 15:16:58 |
| User entered 'No (N)' | System | 25 Sep 2020 15:16:36 |

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:25:19

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 15:41:17 |
| Reviewed for Safety. | (b) (4), (b) (6) | 25 Sep 2020 15:16:58 |
| User entered 'No (N)' | System | 25 Sep 2020 15:16:36 |

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:25:19

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 24 Nov 2020 15:41:17 |
| | | |
| Reviewed for Safety. | (b) (4), (b) (6) | 25 Sep 2020 15:16:58 |
| | | |
| User entered 'Frank' | System | 25 Sep 2020 15:16:36 |

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:25:19

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 15:41:17 |
| Reviewed for Safety. | (b) (4), (b) (6) | 25 Sep 2020 15:16:58 |
| User entered 'Eder' | System | 25 Sep 2020 15:16:36 |

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:25:19

[Site Address: Street](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 15:41:17 |
| Reviewed for Safety. | (b) (4), (b) (6) | 25 Sep 2020 15:16:58 |
| User entered '1290 Upper Front Street' | System | 25 Sep 2020 15:16:36 |

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:25:19

[Site Address: City](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 15:41:17 |
| Reviewed for Safety. | (b) (4), (b) (6) | 25 Sep 2020 15:16:58 |
| User entered 'Binghamton' | System | 25 Sep 2020 15:16:36 |

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:25:19

[Site Address: State](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 15:41:17 |
| Reviewed for Safety. | (b) (4), (b) (6) | 25 Sep 2020 15:16:58 |
| User entered 'NY' | System | 25 Sep 2020 15:16:36 |

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:25:19

[Site Address: Postal Code](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 15:41:17 |
| Reviewed for Safety. | (b) (4), (b) (6) | 25 Sep 2020 15:16:58 |
| User entered '13901' | System | 25 Sep 2020 15:16:36 |

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:25:19

[Investigator Country](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 15:41:17 |
| Reviewed for Safety. | (b) (4), (b) (6) | 13 Oct 2020 13:01:35 |
| User entered 'US' | System | 25 Sep 2020 15:17:05 |

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:25:19

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '4' | System | 30 Oct 2020 14:36:18 |
| User entered '3' | System | 14 Oct 2020 14:03:44 |
| User entered '2' | System | 13 Oct 2020 13:01:46 |
| User entered '1' | System | 25 Sep 2020 15:17:05 |

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:25:19

[SAEID](#)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 15:41:17 |
| Reviewed for Safety. | (b) (4), (b) (6) | 25 Sep 2020 15:16:58 |
| User entered 'USA-US059-2020-MRNA-1273-P301000004' | System | 25 Sep 2020 15:16:36 |

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:25:19

Serious

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 15:41:17 |
| Reviewed for Safety. | (b) (4), (b) (6) | 25 Sep 2020 15:16:58 |
| User entered 'Yes (Y)' | System | 25 Sep 2020 15:16:36 |

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:25:19

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 15:41:17 |
| Reviewed for Safety. | (b) (4), (b) (6) | 25 Sep 2020 15:16:58 |
| User entered 'No (N)' | System | 25 Sep 2020 15:16:36 |

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:25:19

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 15:41:17 |
| Reviewed for Safety. | (b) (4), (b) (6) | 25 Sep 2020 15:16:58 |
| User entered 'No (N)' | System | 25 Sep 2020 15:16:36 |

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:25:19

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 15:41:17 |
| Reviewed for Safety. | (b) (4), (b) (6) | 25 Sep 2020 15:16:58 |
| User entered 'Yes (Y)' | System | 25 Sep 2020 15:16:36 |

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:25:19

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 15:41:17 |
| Reviewed for Safety. | (b) (4), (b) (6) | 25 Sep 2020 15:16:58 |
| User entered 'No (N)' | System | 25 Sep 2020 15:16:36 |

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:25:19

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 15:41:17 |
| Reviewed for Safety. | (b) (4), (b) (6) | 25 Sep 2020 15:16:58 |
| User entered 'No (N)' | System | 25 Sep 2020 15:16:36 |

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:25:19

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 15:41:17 |
| Reviewed for Safety. | (b) (4), (b) (6) | 25 Sep 2020 15:16:58 |
| User entered 'No (N)' | System | 25 Sep 2020 15:16:36 |

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:25:19

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 15:41:17 |
| Reviewed for Safety. | (b) (4), (b) (6) | 25 Sep 2020 15:16:58 |
| User entered 'Frank' | System | 25 Sep 2020 15:16:36 |

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:25:19

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 15:41:17 |
| Reviewed for Safety. | (b) (4), (b) (6) | 25 Sep 2020 15:16:58 |
| User entered 'Eder' | System | 25 Sep 2020 15:16:36 |

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:25:19

[Site Address: Street](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 15:41:17 |
| Reviewed for Safety. | (b) (4), (b) (6) | 25 Sep 2020 15:16:58 |
| User entered '1290 Upper Front Street' | System | 25 Sep 2020 15:16:36 |

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:25:19

[Site Address: City](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 15:41:17 |
| Reviewed for Safety. | (b) (4), (b) (6) | 25 Sep 2020 15:16:58 |
| User entered 'Binghamton' | System | 25 Sep 2020 15:16:36 |

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:25:19

[Site Address: State](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 15:41:17 |
| Reviewed for Safety. | (b) (4), (b) (6) | 25 Sep 2020 15:16:58 |
| User entered 'NY' | System | 25 Sep 2020 15:16:36 |

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:25:19

[Site Address: Postal Code](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 15:41:17 |
| Reviewed for Safety. | (b) (4), (b) (6) | 25 Sep 2020 15:16:58 |
| User entered '13901' | System | 25 Sep 2020 15:16:36 |

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:25:19

[Investigator Country](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 15:41:17 |
| Reviewed for Safety. | (b) (4), (b) (6) | 13 Oct 2020 13:01:35 |
| User entered 'US' | System | 25 Sep 2020 15:17:05 |

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:25:19

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '4' | System | 30 Oct 2020 14:36:18 |
| User entered '3' | System | 14 Oct 2020 14:03:44 |
| User entered '2' | System | 13 Oct 2020 13:01:46 |
| User entered '1' | System | 25 Sep 2020 15:17:05 |

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:25:19

[Date of submission \(Pre-filled from custom function\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|-----------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 15:41:17 |
| User entered '25/Sep/2020 15:17' | System | 25 Sep 2020 15:17:05 |

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:25:19

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. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 15:41:17 |
| Reviewed for Safety. | (b) (4), (b) (6) | 13 Oct 2020 13:01:35 |
| User entered 'I' | (b) (4), (b) (6) | 25 Sep 2020 15:17:05 |

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:25:19

[SAEID](#)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 15:41:17 |
| Reviewed for Safety. | (b) (4), (b) (6) | 25 Sep 2020 15:16:58 |
| User entered 'USA-US059-2020-MRNA-1273-P301000004' | System | 25 Sep 2020 15:16:36 |

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:25:19

Serious

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 15:41:17 |
| Reviewed for Safety. | (b) (4), (b) (6) | 25 Sep 2020 15:16:58 |
| User entered 'Yes (Y)' | System | 25 Sep 2020 15:16:36 |

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:25:19

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 15:41:17 |
| Reviewed for Safety. | (b) (4), (b) (6) | 25 Sep 2020 15:16:58 |
| User entered 'No (N)' | System | 25 Sep 2020 15:16:36 |

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:25:19

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 15:41:17 |
| Reviewed for Safety. | (b) (4), (b) (6) | 25 Sep 2020 15:16:58 |
| User entered 'No (N)' | System | 25 Sep 2020 15:16:36 |

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:25:19

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 15:41:17 |
| Reviewed for Safety. | (b) (4), (b) (6) | 25 Sep 2020 15:16:58 |
| User entered 'Yes (Y)' | System | 25 Sep 2020 15:16:36 |

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:25:19

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 15:41:17 |
| Reviewed for Safety. | (b) (4), (b) (6) | 25 Sep 2020 15:16:58 |
| User entered 'No (N)' | System | 25 Sep 2020 15:16:36 |

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:25:19

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 15:41:17 |
| Reviewed for Safety. | (b) (4), (b) (6) | 25 Sep 2020 15:16:58 |
| User entered 'No (N)' | System | 25 Sep 2020 15:16:36 |

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:25:19

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 15:41:17 |
| Reviewed for Safety. | (b) (4), (b) (6) | 25 Sep 2020 15:16:58 |
| User entered 'No (N)' | System | 25 Sep 2020 15:16:36 |

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:25:19

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 24 Nov 2020 15:41:17 |
| | | |
| Reviewed for Safety. | (b) (4), (b) (6) | 25 Sep 2020 15:16:58 |
| | | |
| User entered 'Frank' | System | 25 Sep 2020 15:16:36 |

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:25:19

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 15:41:17 |
| Reviewed for Safety. | (b) (4), (b) (6) | 25 Sep 2020 15:16:58 |
| User entered 'Eder' | System | 25 Sep 2020 15:16:36 |

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:25:19

[Site Address: Street](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 15:41:17 |
| Reviewed for Safety. | (b) (4), (b) (6) | 25 Sep 2020 15:16:58 |
| User entered '1290 Upper Front Street' | System | 25 Sep 2020 15:16:36 |

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:25:19

[Site Address: City](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 15:41:17 |
| Reviewed for Safety. | (b) (4), (b) (6) | 25 Sep 2020 15:16:58 |
| User entered 'Binghamton' | System | 25 Sep 2020 15:16:36 |

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:25:19

[Site Address: State](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 15:41:17 |
| Reviewed for Safety. | (b) (4), (b) (6) | 25 Sep 2020 15:16:58 |
| User entered 'NY' | System | 25 Sep 2020 15:16:36 |

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:25:19

[Site Address: Postal Code](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 15:41:17 |
| Reviewed for Safety. | (b) (4), (b) (6) | 25 Sep 2020 15:16:58 |
| User entered '13901' | System | 25 Sep 2020 15:16:36 |

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:25:19

[Investigator Country](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 15:41:17 |
| Reviewed for Safety. | (b) (4), (b) (6) | 13 Oct 2020 13:01:35 |
| User entered 'US' | System | 25 Sep 2020 15:17:05 |

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:25:19

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '4' | System | 30 Oct 2020 14:36:18 |
| User entered '3' | System | 14 Oct 2020 14:03:44 |
| User entered '2' | System | 13 Oct 2020 13:01:46 |
| User entered '1' | System | 25 Sep 2020 15:17:05 |

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:25:19

[Date of submission \(Pre-filled from custom function\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|-----------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 15:41:17 |
| User entered '13/Oct/2020 13:01' | System | 13 Oct 2020 13:01:46 |

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:25:19

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. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 15:41:17 |
| Reviewed for Safety. | (b) (4), (b) (6) | 14 Oct 2020 14:03:34 |
| User entered 'I' | (b) (4), (b) (6) | 13 Oct 2020 13:01:46 |

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:25:19

[SAEID](#)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 15:41:17 |
| Reviewed for Safety. | (b) (4), (b) (6) | 25 Sep 2020 15:16:58 |
| User entered 'USA-US059-2020-MRNA-1273-P301000004' | System | 25 Sep 2020 15:16:36 |

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:25:19

Serious

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 15:41:17 |
| Reviewed for Safety. | (b) (4), (b) (6) | 25 Sep 2020 15:16:58 |
| User entered 'Yes (Y)' | System | 25 Sep 2020 15:16:36 |

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:25:19

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 15:41:17 |
| Reviewed for Safety. | (b) (4), (b) (6) | 25 Sep 2020 15:16:58 |
| User entered 'No (N)' | System | 25 Sep 2020 15:16:36 |

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:25:19

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 15:41:17 |
| Reviewed for Safety. | (b) (4), (b) (6) | 25 Sep 2020 15:16:58 |
| User entered 'No (N)' | System | 25 Sep 2020 15:16:36 |

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:25:19

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 15:41:17 |
| Reviewed for Safety. | (b) (4), (b) (6) | 25 Sep 2020 15:16:58 |
| User entered 'Yes (Y)' | System | 25 Sep 2020 15:16:36 |

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:25:19

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 15:41:17 |
| Reviewed for Safety. | (b) (4), (b) (6) | 25 Sep 2020 15:16:58 |
| User entered 'No (N)' | System | 25 Sep 2020 15:16:36 |

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:25:19

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 15:41:17 |
| Reviewed for Safety. | (b) (4), (b) (6) | 25 Sep 2020 15:16:58 |
| User entered 'No (N)' | System | 25 Sep 2020 15:16:36 |

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:25:19

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 15:41:17 |
| Reviewed for Safety. | (b) (4), (b) (6) | 25 Sep 2020 15:16:58 |
| User entered 'No (N)' | System | 25 Sep 2020 15:16:36 |

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:25:19

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 15:41:17 |
| Reviewed for Safety. | (b) (4), (b) (6) | 25 Sep 2020 15:16:58 |
| User entered 'Frank' | System | 25 Sep 2020 15:16:36 |

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:25:19

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 15:41:17 |
| Reviewed for Safety. | (b) (4), (b) (6) | 25 Sep 2020 15:16:58 |
| User entered 'Eder' | System | 25 Sep 2020 15:16:36 |

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:25:19

[Site Address: Street](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 15:41:17 |
| Reviewed for Safety. | (b) (4), (b) (6) | 25 Sep 2020 15:16:58 |
| User entered '1290 Upper Front Street' | System | 25 Sep 2020 15:16:36 |

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:25:19

[Site Address: City](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 15:41:17 |
| Reviewed for Safety. | (b) (4), (b) (6) | 25 Sep 2020 15:16:58 |
| User entered 'Binghamton' | System | 25 Sep 2020 15:16:36 |

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:25:19

[Site Address: State](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 15:41:17 |
| Reviewed for Safety. | (b) (4), (b) (6) | 25 Sep 2020 15:16:58 |
| User entered 'NY' | System | 25 Sep 2020 15:16:36 |

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:25:19

[Site Address: Postal Code](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 15:41:17 |
| Reviewed for Safety. | (b) (4), (b) (6) | 25 Sep 2020 15:16:58 |
| User entered '13901' | System | 25 Sep 2020 15:16:36 |

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:25:19

[Investigator Country](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 15:41:17 |
| Reviewed for Safety. | (b) (4), (b) (6) | 13 Oct 2020 13:01:35 |
| User entered 'US' | System | 25 Sep 2020 15:17:05 |

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:25:19

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '4' | System | 30 Oct 2020 14:36:18 |
| User entered '3' | System | 14 Oct 2020 14:03:44 |
| User entered '2' | System | 13 Oct 2020 13:01:46 |
| User entered '1' | System | 25 Sep 2020 15:17:05 |

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:25:19

[Date of submission \(Pre-filled from custom function\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|-----------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 15:41:17 |
| User entered '14/Oct/2020 10:03' | System | 14 Oct 2020 14:03:44 |

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:25:19

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. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 15:41:17 |
| Reviewed for Safety. | (b) (4), (b) (6) | 30 Oct 2020 14:36:10 |
| User entered 'I' | (b) (4), (b) (6) | 14 Oct 2020 14:03:44 |

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:25:19

[SAEID](#)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 15:41:17 |
| Reviewed for Safety. | (b) (4), (b) (6) | 25 Sep 2020 15:16:58 |
| User entered 'USA-US059-2020-MRNA-1273-P301000004' | System | 25 Sep 2020 15:16:36 |

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:25:19

Serious

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 15:41:17 |
| Reviewed for Safety. | (b) (4), (b) (6) | 25 Sep 2020 15:16:58 |
| User entered 'Yes (Y)' | System | 25 Sep 2020 15:16:36 |

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:25:19

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 15:41:17 |
| Reviewed for Safety. | (b) (4), (b) (6) | 25 Sep 2020 15:16:58 |
| User entered 'No (N)' | System | 25 Sep 2020 15:16:36 |

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:25:19

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 15:41:17 |
| Reviewed for Safety. | (b) (4), (b) (6) | 25 Sep 2020 15:16:58 |
| User entered 'No (N)' | System | 25 Sep 2020 15:16:36 |

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:25:19

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 15:41:17 |
| Reviewed for Safety. | (b) (4), (b) (6) | 25 Sep 2020 15:16:58 |
| User entered 'Yes (Y)' | System | 25 Sep 2020 15:16:36 |

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:25:19

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 15:41:17 |
| Reviewed for Safety. | (b) (4), (b) (6) | 25 Sep 2020 15:16:58 |
| User entered 'No (N)' | System | 25 Sep 2020 15:16:36 |

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:25:19

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 15:41:17 |
| Reviewed for Safety. | (b) (4), (b) (6) | 25 Sep 2020 15:16:58 |
| User entered 'No (N)' | System | 25 Sep 2020 15:16:36 |

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:25:19

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 15:41:17 |
| Reviewed for Safety. | (b) (4), (b) (6) | 25 Sep 2020 15:16:58 |
| User entered 'No (N)' | System | 25 Sep 2020 15:16:36 |

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:25:19

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 15:41:17 |
| Reviewed for Safety. | (b) (4), (b) (6) | 25 Sep 2020 15:16:58 |
| User entered 'Frank' | System | 25 Sep 2020 15:16:36 |

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:25:19

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 15:41:17 |
| Reviewed for Safety. | (b) (4), (b) (6) | 25 Sep 2020 15:16:58 |
| User entered 'Eder' | System | 25 Sep 2020 15:16:36 |

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:25:19

[Site Address: Street](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 15:41:17 |
| Reviewed for Safety. | (b) (4), (b) (6) | 25 Sep 2020 15:16:58 |
| User entered '1290 Upper Front Street' | System | 25 Sep 2020 15:16:36 |

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:25:19

[Site Address: City](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 15:41:17 |
| Reviewed for Safety. | (b) (4), (b) (6) | 25 Sep 2020 15:16:58 |
| User entered 'Binghamton' | System | 25 Sep 2020 15:16:36 |

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:25:19

[Site Address: State](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 15:41:17 |
| Reviewed for Safety. | (b) (4), (b) (6) | 25 Sep 2020 15:16:58 |
| User entered 'NY' | System | 25 Sep 2020 15:16:36 |

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:25:19

[Site Address: Postal Code](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 15:41:17 |
| Reviewed for Safety. | (b) (4), (b) (6) | 25 Sep 2020 15:16:58 |
| User entered '13901' | System | 25 Sep 2020 15:16:36 |

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:25:19

[Investigator Country](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 15:41:17 |
| Reviewed for Safety. | (b) (4), (b) (6) | 13 Oct 2020 13:01:35 |
| User entered 'US' | System | 25 Sep 2020 15:17:05 |

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:25:19

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '4' | System | 30 Oct 2020 14:36:18 |
| User entered '3' | System | 14 Oct 2020 14:03:44 |
| User entered '2' | System | 13 Oct 2020 13:01:46 |
| User entered '1' | System | 25 Sep 2020 15:17:05 |

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 17:25:19

[Date of submission \(Pre-filled from custom function\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|-----------------------------|----------------------|
| User signature succeeded. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 15:41:17 |
| User entered '30/Oct/2020 10:36' | System | 30 Oct 2020 14:36:18 |

US3402284

Folder: SAE USA-US059-2020-MRNA-1273-P301000004

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 17:25:19

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. | Frank Eder (b) (4) | 26 Apr 2021 23:03:43 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 24 Nov 2020 15:41:17 |
| User entered 'I' | (b) (4), (b) (6) | 30 Oct 2020 14:36:18 |