

US3592229 (Prod: Alliance for Multispecialty Research, LLC - East Wichita)

Generated By: KC Joubran

Generated On: 10 Jun 2021 08:21:23

All time stamps listed in this document are displayed in GMT

US3592229

Form: Participant Creation

Data signed: (b) (4) 28 Apr 2021 09:35:59

Generated On: 10 Jun 2021 08:21:23

[Participant ID](#)

US3592229

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

US3592229

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 05 Mar 2021 16:30:19

Generated On: 10 Jun 2021 08:21:23

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

US3592229

Folder: Screening

Form: Demographics

Data signed: (b) (4) 05 Mar 2021 16:30:18

Generated On: 10 Jun 2021 08:21:23

| | |
|---|--|
| Date of Birth (MMM yyyy) | (b) (6) 1967 |
| Age | 52 |
| Age Units | YEARS |
| Age (Derived) | 52 |
| Sex | Female <input checked="" type="radio"/> Male <input type="radio"/> |
| Ethnicity | Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/> |
| Race (Check All That Apply) | |
| White | True |
| Black | False |
| Asian | False |
| American Indian or Alaska Native | False |
| Native Hawaiian or other Pacific Islander | False |
| Other | False |
| If race is Other, specify _____ | |
| Unknown | False |
| Not reported | False |

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 05 Mar 2021 16:30:18

Generated On: 10 Jun 2021 08:21:23

| | |
|---|--|
| Date of Informed Consent (<i>dd MMM yyyy</i>) | 18 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) 05 Mar 2021 16:30:18

Generated On: 10 Jun 2021 08:21:23

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 05 Mar 2021 16:30:19

Generated On: 10 Jun 2021 08:21:23

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 05 Mar 2021 16:30:18

Generated On: 10 Jun 2021 08:21:23

| | |
|---|--|
| Condition | ALLERGIC RHINITIS |
| Start date (dd MMM yyyy) | UN MAR 1988 |
| 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) | MAR 1988 |
| Start Year (derived) | 1988 |
| Stop Month and Year (derived) | |
| Stop Year (derived) | |

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 05 Mar 2021 16:30:18

Generated On: 10 Jun 2021 08:21:23

| | |
|---|--|
| Condition | HYPERTENSION |
| Start date (dd MMM yyyy) | UN MAR 1988 |
| 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) | MAR 1988 |
| Start Year (derived) | 1988 |
| Stop Month and Year (derived) | _____ |
| Stop Year (derived) | _____ |

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 05 Mar 2021 16:30:18

Generated On: 10 Jun 2021 08:21:23

| | |
|---|--|
| Condition | HYPERCHOLESTEROLEMIA |
| Start date (dd MMM yyyy) | UN JAN 2008 |
| 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 2008 |
| Start Year (derived) | 2008 |
| Stop Month and Year (derived) | _____ |
| Stop Year (derived) | _____ |

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 05 Mar 2021 16:30:18

Generated On: 10 Jun 2021 08:21:23

| | |
|---|--|
| Condition | GASTROESOPHOGEAL REFLUX DISEASE |
| Start date (dd MMM yyyy) | UN MAR 2014 |
| Start date completely unknown | False |
| Condition ongoing at study entry | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| If No, please specify the stop date (dd MMM yyyy) | |
| Stop date completely unknown | False |
| Start Month and Year (derived) | MAR 2014 |
| Start Year (derived) | 2014 |
| Stop Month and Year (derived) | |
| Stop Year (derived) | |

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 05 Mar 2021 16:30:18

Generated On: 10 Jun 2021 08:21:23

| | |
|---|--|
| Condition | POSTMENOPAUSAL |
| Start date (dd MMM yyyy) | UN JAN 2018 |
| 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 2018 |
| Start Year (derived) | 2018 |
| Stop Month and Year (derived) | |
| Stop Year (derived) | |

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 05 Mar 2021 16:30:18

Generated On: 10 Jun 2021 08:21:23

| | |
|---|--|
| Condition | DEPRESSION |
| Start date (dd MMM yyyy) | UN MAR 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) | MAR 2016 |
| Start Year (derived) | 2016 |
| Stop Month and Year (derived) | _____ |
| Stop Year (derived) | _____ |

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 05 Mar 2021 16:30:18

Generated On: 10 Jun 2021 08:21:23

| | |
|---|--|
| Condition | INSOMNIA |
| Start date (dd MMM yyyy) | UN MAR 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) | MAR 2016 |
| Start Year (derived) | 2016 |
| Stop Month and Year (derived) | _____ |
| Stop Year (derived) | _____ |

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 05 Mar 2021 16:30:18

Generated On: 10 Jun 2021 08:21:23

| | |
|---|--|
| Condition | ATTENTION DEFICIENCY DISORDER |
| Start date (dd MMM yyyy) | UN MAR 2014 |
| Start date completely unknown | False |
| Condition ongoing at study entry | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| If No, please specify the stop date (dd MMM yyyy) | |
| Stop date completely unknown | False |
| Start Month and Year (derived) | MAR 2014 |
| Start Year (derived) | 2014 |
| Stop Month and Year (derived) | |
| Stop Year (derived) | |

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 05 Mar 2021 16:30:18

Generated On: 10 Jun 2021 08:21:23

| | |
|---|--|
| Condition | SUBGLOTTIC STENOSIS |
| Start date (dd MMM yyyy) | UN MAR 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 MAR 2018 |
| Stop date completely unknown | False |
| Start Month and Year (derived) | MAR 2018 |
| Start Year (derived) | 2018 |
| Stop Month and Year (derived) | MAR 2018 |
| Stop Year (derived) | 2018 |

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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 05 Mar 2021 16:30:18

Generated On: 10 Jun 2021 08:21:23

| | |
|---|--|
| Condition | ENDOSCOPIC DILATION |
| Start date (dd MMM yyyy) | UN MAR 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 MAR 2018 |
| Stop date completely unknown | False |
| Start Month and Year (derived) | MAR 2018 |
| Start Year (derived) | 2018 |
| Stop Month and Year (derived) | MAR 2018 |
| Stop Year (derived) | 2018 |

US3592229

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 05 Mar 2021 16:30:19

Generated On: 10 Jun 2021 08:21:23

| | |
|-------------------------------------|--------------------------------------|
| Were vital signs assessed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Date of assessment (dd MMM yyyy) | 18 AUG 2020 |
| Time of assessment (00:00-23:59) | 17:23 (24 HR) |
| Vital Signs Date and Time (derived) | 18 AUG 2020 17:23 |
| Height (xxx.x) | 169.0 cm |
| Weight (xxx.x) | 100.8 kg |
| BMI (xxx.x) | 35.29288 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) 05 Mar 2021 16:30:19

Generated On: 10 Jun 2021 08:21:23

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

18 AUG 2020

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 05 Mar 2021 16:30:18

Generated On: 10 Jun 2021 08:21:23

Date of assessment (dd MMM yyyy) 18 AUG 2020

Is the participant of childbearing potential? Yes ☐
No ☒

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

If Partner medically sterile or Other, specify _____

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

Date of surgery unknown False

If Post-menopausal, date of last menstruation (dd MMM yyyy) UN JAN 2018

Date of last menstruation unknown False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 05 Mar 2021 16:30:19

Generated On: 10 Jun 2021 08:21:23

Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 05 Mar 2021 16:30:19

Generated On: 10 Jun 2021 08:21:23

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 05 Mar 2021 16:00:39

Generated On: 10 Jun 2021 08:21:23

| | |
|---|---|
| Was this visit performed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Visit date (dd MMM yyyy) | 18 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) 05 Mar 2021 16:00:39

Generated On: 10 Jun 2021 08:21:23

What was the date of randomization? (dd MMM yyyy) 18 AUG 2020

What was the participant's randomization number? 105768

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) 05 Mar 2021 16:00:39

Generated On: 10 Jun 2021 08:21:23

| | |
|--------|---------------|
| 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) 05 Mar 2021 16:00:39

Generated On: 10 Jun 2021 08:21:23

| | |
|-------------------------------------|--|
| 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) | 18 AUG 2020 |
| Time of assessment (00:00-23:59) | 17:23 (24 HR) |
| Vital Signs Date and Time (derived) | 18 AUG 2020 17:23 |
| Temperature (xxx.x) | 98.3 F |
| Route of measurement | Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/> |
| If Other, specify | |
| Pulse (xxx) | 77 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 16 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 172 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 97 mmHg |
| Diastolic Blood Pressure units | MMHG |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 05 Mar 2021 16:00:39

Generated On: 10 Jun 2021 08:21:23

| | |
|-------------------------------------|--|
| Height | ND - Not Done |
| Weight | ND - Not Done |
| Timepoint | Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/> |
| Were vital signs assessed? | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Date of assessment (dd MMM yyyy) | 18 AUG 2020 |
| Time of assessment (00:00-23:59) | 18:57 (24 HR) |
| Vital Signs Date and Time (derived) | 18 AUG 2020 18:57 |
| Temperature (xxx.x) | 97.9 F |
| Route of measurement | Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/> |
| If Other, specify | |
| Pulse (xxx) | 80 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 16 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 159 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 75 mmHg |
| Diastolic Blood Pressure units | MMHG |

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 05 Mar 2021 16:00:39

Generated On: 10 Jun 2021 08:21:23

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 05 Mar 2021 16:00:39

Generated On: 10 Jun 2021 08:21:23

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 18 AUG 2020

What was the treatment time? (00:00-23:59) 18:26 (24 HR)

Treatment Date and Time (derived) 18 AUG 2020 18:26

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Mar 2021 16:00:39

Generated On: 10 Jun 2021 08:21:23

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

| | |
|-------------------------------|-------------|
| Collection date (dd MMM yyyy) | 18 AUG 2020 |
|-------------------------------|-------------|

| | |
|-------------------------------|---------------|
| Collection time (00:00-23:59) | 18:07 (24 HR) |
|-------------------------------|---------------|

| | |
|------------------------------------|-------------------|
| Collection date and time (derived) | 18 AUG 2020 18:07 |
|------------------------------------|-------------------|

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 05 Mar 2021 16:00:39

Generated On: 10 Jun 2021 08:21:23

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

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 16:00:39

Generated On: 10 Jun 2021 08:21:23

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: 10 Jun 2021 08:21:23

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

18 AUG 2020 19:00

PC Open Date & Time

18 AUG 2020 18:46

PC Close Date & Time

18 AUG 2020 21:16

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:21:23

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 96.8 °F

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

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

| | |
|----------------------|-------------------|
| PC Time Stamp | 19 AUG 2020 06:17 |
| PC Open Date & Time | 18 AUG 2020 22:11 |
| PC Close Date & Time | 19 AUG 2020 11:59 |

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:21:23

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

97.9 °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

19 AUG 2020 15:51

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3592229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:21:23

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

97.6 °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

21 AUG 2020 07:18

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3592229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:21:23

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

22 AUG 2020 07:39

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3592229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:21:23

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

23 AUG 2020 08:50

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3592229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:21:23

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

100.6 °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

23 AUG 2020 14:20

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3592229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:21:23

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

24 AUG 2020 15:50

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3592229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:21:23

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

18 AUG 2020 19:01

PC Open Date & Time

18 AUG 2020 18:46

PC Close Date & Time

18 AUG 2020 21:16

US3592229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:21:23

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

19 AUG 2020 06:17

PC Open Date & Time

18 AUG 2020 22:11

PC Close Date & Time

19 AUG 2020 11:59

US3592229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:21:23

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

19 AUG 2020 15:51

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3592229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:21:23

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

21 AUG 2020 07:18

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3592229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:21:23

| TIMEPOINT | DAY 4 |
|--|---------------------------------------|
| Please record - PAIN AT INJECTION SITE. | None <input checked="" type="radio"/> |
| Please select one response below | |
| Does not interfere with activity | <input type="radio"/> |
| Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity | <input type="radio"/> |
| Any use of prescription pain reliever or prevents daily activity | <input type="radio"/> |
| Is there any REDNESS AT INJECTION SITE? | Yes <input type="radio"/> |
| | No <input checked="" type="radio"/> |
| Is there any SWELLING/HARDNESS AT INJECTION SITE? | Yes <input type="radio"/> |
| | No <input checked="" type="radio"/> |
| Please record - UNDERARM GLAND SWELLING OR TENDERNESS. | None <input checked="" type="radio"/> |
| Please select one response below | |
| Does not interfere with activity | <input type="radio"/> |
| Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity | <input type="radio"/> |
| Any use of prescription pain reliever or prevents daily activity | <input type="radio"/> |
| PC Time Stamp | 22 AUG 2020 07:39 |
| PC Open Date & Time | 21 AUG 2020 12:00 |
| PC Close Date & Time | 22 AUG 2020 11:59 |

US3592229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:21:23

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

23 AUG 2020 08:51

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3592229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:21:23

| TIMEPOINT | DAY 6 |
|--|---------------------------------------|
| Please record - PAIN AT INJECTION SITE. | None <input checked="" type="radio"/> |
| Please select one response below | |
| Does not interfere with activity | <input type="radio"/> |
| Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity | <input type="radio"/> |
| Any use of prescription pain reliever or prevents daily activity | <input type="radio"/> |
| Is there any REDNESS AT INJECTION SITE? | Yes <input type="radio"/> |
| | No <input checked="" type="radio"/> |
| Is there any SWELLING/HARDNESS AT INJECTION SITE? | Yes <input type="radio"/> |
| | No <input checked="" type="radio"/> |
| Please record - UNDERARM GLAND SWELLING OR TENDERNESS. | None <input checked="" type="radio"/> |
| Please select one response below | |
| Does not interfere with activity | <input type="radio"/> |
| Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity | <input type="radio"/> |
| Any use of prescription pain reliever or prevents daily activity | <input type="radio"/> |
| PC Time Stamp | 23 AUG 2020 14:21 |
| PC Open Date & Time | 23 AUG 2020 12:00 |
| PC Close Date & Time | 24 AUG 2020 11:59 |

US3592229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:21:23

| TIMEPOINT | DAY 7 |
|--|---------------------------------------|
| Please record - PAIN AT INJECTION SITE. | None <input checked="" type="radio"/> |
| Please select one response below | |
| Does not interfere with activity | <input type="radio"/> |
| Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity | <input type="radio"/> |
| Any use of prescription pain reliever or prevents daily activity | <input type="radio"/> |
| Is there any REDNESS AT INJECTION SITE? | Yes <input type="radio"/> |
| | No <input checked="" type="radio"/> |
| Is there any SWELLING/HARDNESS AT INJECTION SITE? | Yes <input type="radio"/> |
| | No <input checked="" type="radio"/> |
| Please record - UNDERARM GLAND SWELLING OR TENDERNESS. | None <input checked="" type="radio"/> |
| Please select one response below | |
| Does not interfere with activity | <input type="radio"/> |
| Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity | <input type="radio"/> |
| Any use of prescription pain reliever or prevents daily activity | <input type="radio"/> |
| PC Time Stamp | 24 AUG 2020 15:50 |
| PC Open Date & Time | 24 AUG 2020 12:00 |
| PC Close Date & Time | 25 AUG 2020 11:59 |

US3592229

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:21:23

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 ☐

US3592229

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:21:23

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

No ☒

Yes ☐

| | |
|----------------------|-------------------|
| PC Time stamp | 18 AUG 2020 19:01 |
| PC Open Date & Time | 18 AUG 2020 18:46 |
| PC Close Date & Time | 18 AUG 2020 21:16 |

US3592229

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:21:23

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 ☐

US3592229

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:21:23

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

No ☒

Yes ☐

| | |
|----------------------|-------------------|
| PC Time stamp | 19 AUG 2020 06:18 |
| PC Open Date & Time | 18 AUG 2020 22:11 |
| PC Close Date & Time | 19 AUG 2020 11:59 |

US3592229

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:21:23

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 ☒

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Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:21:23

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 19 AUG 2020 15:52 |
| PC Open Date & Time | 19 AUG 2020 12:00 |
| PC Close Date & Time | 20 AUG 2020 11:59 |

US3592229

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:21:23

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3592229

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:21:23

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 21 AUG 2020 07:19 |
| PC Open Date & Time | 20 AUG 2020 12:00 |
| PC Close Date & Time | 21 AUG 2020 11:59 |

US3592229

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:21:23

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

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EAB) (1725)

US3592229

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:21:23

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 22 AUG 2020 07:40 |
| PC Open Date & Time | 21 AUG 2020 12:00 |
| PC Close Date & Time | 22 AUG 2020 11:59 |

US3592229

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:21:23

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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US3592229

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:21:23

| | | |
|----------------------|-------------------|------------------------------|
| | | Yes <input type="checkbox"/> |
| PC Time stamp | 23 AUG 2020 08:52 | |
| PC Open Date & Time | 22 AUG 2020 12:00 | |
| PC Close Date & Time | 23 AUG 2020 11:59 | |

US3592229

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:21:23

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 ☐

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EAB) (1725)

US3592229

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:21:23

| | |
|----------------------|---------------------------|
| | Yes <input type="radio"/> |
| PC Time stamp | 23 AUG 2020 14:22 |
| PC Open Date & Time | 23 AUG 2020 12:00 |
| PC Close Date & Time | 24 AUG 2020 11:59 |

US3592229

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:21:23

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3592229

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:21:23

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 24 AUG 2020 15:50 |
| PC Open Date & Time | 24 AUG 2020 12:00 |
| PC Close Date & Time | 25 AUG 2020 11:59 |

US3592229

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 16:30:18

Generated On: 10 Jun 2021 08:21:23

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

26 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3592229

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 16:30:18

Generated On: 10 Jun 2021 08:21:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3592229

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 16:30:18

Generated On: 10 Jun 2021 08:21:23

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 1 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3592229

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 16:30:18

Generated On: 10 Jun 2021 08:21:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3592229

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 16:30:18

Generated On: 10 Jun 2021 08:21:23

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 8 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3592229

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 16:30:18

Generated On: 10 Jun 2021 08:21:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3592229

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 05 Mar 2021 16:00:39

Generated On: 10 Jun 2021 08:21:23

| | |
|---|---------------------------------------|
| Was this visit performed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Visit date (dd MMM yyyy) | 15 SEP 2020 |
| Was visit performed at the participant's home or at the clinic? | Home <input checked="" type="radio"/> |
| | Clinic <input type="radio"/> |
| Folder OID | VISIT2 |

US3592229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 05 Mar 2021 16:00:39

Generated On: 10 Jun 2021 08:21:23

| | |
|-------------------------------------|---|
| 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) | 15 SEP 2020 |
| Time of assessment (00:00-23:59) | 7:19 (24 HR) |
| Vital Signs Date and Time (derived) | 15 SEP 2020 7:19 |
| Temperature (xxx.x) | 97.9 F |
| Route of measurement | Oral <input checked="" type="radio"/> |
| | Axillary <input type="radio"/> |
| | Other <input type="radio"/> |
| If Other, specify | |
| Pulse (xxx) | 74 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 16 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 128 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 83 mmHg |
| Diastolic Blood Pressure units | MMHG |

US3592229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 05 Mar 2021 16:00:39

Generated On: 10 Jun 2021 08:21:23

| | |
|-------------------------------------|--|
| Timepoint | Pre-Dose <input type="radio"/> |
| | Post-Dose <input checked="" type="radio"/> |
| Were vital signs assessed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Date of assessment (dd MMM yyyy) | 15 SEP 2020 |
| Time of assessment (00:00-23:59) | 8:38 (24 HR) |
| Vital Signs Date and Time (derived) | 15 SEP 2020 8:38 |
| Temperature (xxx.x) | 97.7 F |
| Route of measurement | Oral <input checked="" type="radio"/> |
| | Axillary <input type="radio"/> |
| | Other <input type="radio"/> |
| If Other, specify | |
| Pulse (xxx) | 73 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 16 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 109 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 77 mmHg |
| Diastolic Blood Pressure units | MMHG |

US3592229

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Mar 2021 16:00:39

Generated On: 10 Jun 2021 08:21:23

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

15 SEP 2020

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

US3592229

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 05 Mar 2021 16:00:39

Generated On: 10 Jun 2021 08:21:23

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) 15 SEP 2020

What was the treatment time? (00:00-23:59) 08:07 (24 HR)

Treatment Date and Time (derived) 15 SEP 2020 08:07

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

US3592229

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Mar 2021 16:00:39

Generated On: 10 Jun 2021 08:21:23

| | |
|------------------------------------|--------------------------------------|
| Was the sample collected? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Collection date (dd MMM yyyy) | 15 SEP 2020 |
| Collection time (00:00-23:59) | 7:39 (24 HR) |
| Collection date and time (derived) | 15 SEP 2020 7:39 |

US3592229

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 05 Mar 2021 16:00:39

Generated On: 10 Jun 2021 08:21:23

| | | | |
|-------------------------------|---------------------------|---------------------------------|------------------------------------|
| Collection date (dd MMM yyyy) | | | 15 SEP 2020 |
| Lab Test | Was the sample collected? | Collection time (00:00 - 23:59) | Collection date and time (derived) |
| Nasopharyngeal Swab 1 | Yes | 7:40 | 15 SEP 2020 7:40 |
| Nasopharyngeal Swab 2 | No | | |

US3592229

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 16:00:39

Generated On: 10 Jun 2021 08:21:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3592229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:21:23

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

15 SEP 2020 08:37

PC Open Date & Time

15 SEP 2020 08:27

PC Close Date & Time

15 SEP 2020 10:57

US3592229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:21:23

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 97.5 °F

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

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

| | |
|----------------------|-------------------|
| PC Time Stamp | 15 SEP 2020 16:23 |
| PC Open Date & Time | 15 SEP 2020 11:52 |
| PC Close Date & Time | 16 SEP 2020 11:59 |

US3592229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:21:23

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

16 SEP 2020 18:20

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3592229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:21:23

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

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

17 SEP 2020 17:38

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3592229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:21:23

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

97.8 °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

18 SEP 2020 17:15

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3592229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:21:23

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °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

19 SEP 2020 18:00

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3592229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:21:23

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

97.8 °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

20 SEP 2020 17:00

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3592229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:21:23

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3592229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:21:23

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

15 SEP 2020 08:38

PC Open Date & Time

15 SEP 2020 08:27

PC Close Date & Time

15 SEP 2020 10:57

US3592229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:21:23

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

15 SEP 2020 16:23

PC Open Date & Time

15 SEP 2020 11:52

PC Close Date & Time

16 SEP 2020 11:59

US3592229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:21:23

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

16 SEP 2020 18:20

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3592229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:21:23

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

17 SEP 2020 17:38

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3592229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:21:23

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

18 SEP 2020 17:16

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3592229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:21:23

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

19 SEP 2020 18:01

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3592229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:21:23

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

20 SEP 2020 17:00

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3592229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:21:23

TIMEPOINT

DAY 7

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3592229

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:21:23

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 ☐

US3592229

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:21:23

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

No ☒

Yes ☐

| | |
|----------------------|-------------------|
| PC Time stamp | 15 SEP 2020 08:38 |
| PC Open Date & Time | 15 SEP 2020 08:27 |
| PC Close Date & Time | 15 SEP 2020 10:57 |

US3592229

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:21:23

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 ☐

US3592229

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:21:23

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

No ☒

Yes ☐

| | |
|----------------------|-------------------|
| PC Time stamp | 15 SEP 2020 16:24 |
| PC Open Date & Time | 15 SEP 2020 11:52 |
| PC Close Date & Time | 16 SEP 2020 11:59 |

US3592229

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:21:23

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 ☒

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EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:21:23

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 16 SEP 2020 18:20 |
| PC Open Date & Time | 16 SEP 2020 12:00 |
| PC Close Date & Time | 17 SEP 2020 11:59 |

US3592229

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:21:23

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3592229

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:21:23

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 17 SEP 2020 17:39 |
| PC Open Date & Time | 17 SEP 2020 12:00 |
| PC Close Date & Time | 18 SEP 2020 11:59 |

US3592229

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:21:23

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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Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:21:23

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 18 SEP 2020 17:16 |
| PC Open Date & Time | 18 SEP 2020 12:00 |
| PC Close Date & Time | 19 SEP 2020 11:59 |

US3592229

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:21:23

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 ☒

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EAB) (1725)

US3592229

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:21:23

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 19 SEP 2020 18:01 |
| PC Open Date & Time | 19 SEP 2020 12:00 |
| PC Close Date & Time | 20 SEP 2020 11:59 |

US3592229

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:21:23

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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US3592229

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:21:23

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 20 SEP 2020 17:01 |
| PC Open Date & Time | 20 SEP 2020 12:00 |
| PC Close Date & Time | 21 SEP 2020 11:59 |

US3592229

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:21:23

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 ☐

US3592229

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:21:23

Yes ☐

PC Time stamp

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3592229

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 16:30:18

Generated On: 10 Jun 2021 08:21:23

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 23 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3592229

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 16:30:18

Generated On: 10 Jun 2021 08:21:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3592229

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 16:00:38

Generated On: 10 Jun 2021 08:21:23

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 30 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3592229

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 16:00:38

Generated On: 10 Jun 2021 08:21:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3592229

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 16:00:38

Generated On: 10 Jun 2021 08:21:23

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 6 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3592229

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 16:00:38

Generated On: 10 Jun 2021 08:21:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3592229

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 05 Mar 2021 16:00:39

Generated On: 10 Jun 2021 08:21:23

| | |
|---|---|
| Was this visit performed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Visit date (dd MMM yyyy) | 15 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 |

US3592229

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 05 Mar 2021 16:00:39

Generated On: 10 Jun 2021 08:21:23

| | |
|-------------------------------------|---------------------------------------|
| Were vital signs assessed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Date of assessment (dd MMM yyyy) | 15 OCT 2020 |
| Time of assessment (00:00-23:59) | 07:22 (24 HR) |
| Vital Signs Date and Time (derived) | 15 OCT 2020 07:22 |
| Temperature (xxx.x) | 98.1 F |
| Route of measurement | Oral <input checked="" type="radio"/> |
| | Axillary <input type="radio"/> |
| | Other <input type="radio"/> |
| If Other, specify | |
| Pulse (xxx) | 71 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 16 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 134 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 87 mmHg |
| Diastolic Blood Pressure units | MMHG |
| Height (derived) | |
| Weight (derived) | |

US3592229

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Mar 2021 16:00:39

Generated On: 10 Jun 2021 08:21:23

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.

US3592229

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Mar 2021 16:00:39

Generated On: 10 Jun 2021 08:21:23

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

15 OCT 2020

Collection time (00:00-23:59)

07:32 (24 HR)

Collection date and time (derived)

15 OCT 2020 07:32

US3592229

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 16:00:39

Generated On: 10 Jun 2021 08:21:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3592229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

| | |
|---|--|
| TIMEPOINT | DAY 64 |
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Date and time of submission | 21 OCT 2020 10:27:44 |
| Patient Cloud Open Date & Time | 18 OCT 2020 00:01 |
| Patient Cloud Close Date & Time | 22 OCT 2020 23:59 |

US3592229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

TIMEPOINT

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 OCT 2020 08:09:20

Patient Cloud Open Date & Time

25 OCT 2020 00:01

Patient Cloud Close Date & Time

29 OCT 2020 23:59

US3592229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

| 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 | 01 NOV 2020 17:56:06 |
| Patient Cloud Open Date & Time | 01 NOV 2020 00:01 |
| Patient Cloud Close Date & Time | 05 NOV 2020 23:59 |

US3592229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

| 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 | 17 NOV 2020 12:38:39 |
| Patient Cloud Open Date & Time | 15 NOV 2020 00:01 |
| Patient Cloud Close Date & Time | 19 NOV 2020 23:59 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

| TIMEPOINT | DAY 96 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input 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 NOV 2020 05:47:44 |
| Patient Cloud Open Date & Time | 19 NOV 2020 00:01 |
| Patient Cloud Close Date & Time | 23 NOV 2020 23:59 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

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

26 NOV 2020 13:38:21

Patient Cloud Open Date & Time

26 NOV 2020 00:01

Patient Cloud Close Date & Time

30 NOV 2020 23:59

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

| 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 | 05 DEC 2020 12:14:57 |
| Patient Cloud Open Date & Time | 03 DEC 2020 00:01 |
| Patient Cloud Close Date & Time | 07 DEC 2020 23:59 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

TIMEPOINT

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

12 DEC 2020 21:42:28

Patient Cloud Open Date & Time

10 DEC 2020 00:01

Patient Cloud Close Date & Time

14 DEC 2020 23:59

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

| | |
|---|--|
| 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 | 17 DEC 2020 05:21:31 |
| Patient Cloud Open Date & Time | 17 DEC 2020 00:01 |
| Patient Cloud Close Date & Time | 21 DEC 2020 23:59 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

TIMEPOINT

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 DEC 2020 12:45:26

Patient Cloud Open Date & Time

24 DEC 2020 00:01

Patient Cloud Close Date & Time

28 DEC 2020 23:59

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

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

03 JAN 2021 17:59:28

Patient Cloud Open Date & Time

31 DEC 2020 00:01

Patient Cloud Close Date & Time

04 JAN 2021 23:59

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

| | |
|---|--|
| 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 | 08 JAN 2021 17:28:28 |
| Patient Cloud Open Date & Time | 07 JAN 2021 00:01 |
| Patient Cloud Close Date & Time | 11 JAN 2021 23:59 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

| | |
|---|--|
| 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 <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 | 14 JAN 2021 05:35:40 |
| Patient Cloud Open Date & Time | 14 JAN 2021 00:01 |
| Patient Cloud Close Date & Time | 18 JAN 2021 23:59 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

TIMEPOINT

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 JAN 2021 18:31:17

Patient Cloud Open Date & Time

21 JAN 2021 00:01

Patient Cloud Close Date & Time

25 JAN 2021 23:59

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

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 ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 JAN 2021 07:24:11

Patient Cloud Open Date & Time

28 JAN 2021 00:01

Patient Cloud Close Date & Time

01 FEB 2021 23:59

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

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

04 FEB 2021 19:39:22

Patient Cloud Open Date & Time

04 FEB 2021 00:01

Patient Cloud Close Date & Time

08 FEB 2021 23:59

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

| TIMEPOINT | DAY 180 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Date and time of submission | 12 FEB 2021 18:24:06 |
| Patient Cloud Open Date & Time | 11 FEB 2021 00:01 |
| Patient Cloud Close Date & Time | 15 FEB 2021 23:59 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

| 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 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 | 18 FEB 2021 05:57:33 |
| Patient Cloud Open Date & Time | 18 FEB 2021 00:01 |
| Patient Cloud Close Date & Time | 22 FEB 2021 23:59 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

| TIMEPOINT | DAY 194 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input checked="" type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Date and time of submission | 27 FEB 2021 23:00:59 |
| Patient Cloud Open Date & Time | 25 FEB 2021 00:01 |
| Patient Cloud Close Date & Time | 01 MAR 2021 23:59 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

| | |
|---|--|
| TIMEPOINT | DAY 201 |
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Date and time of submission | 06 MAR 2021 18:11:05 |
| Patient Cloud Open Date & Time | 04 MAR 2021 00:01 |
| Patient Cloud Close Date & Time | 08 MAR 2021 23:59 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

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

14 MAR 2021 18:16:54

Patient Cloud Open Date & Time

11 MAR 2021 00:01

Patient Cloud Close Date & Time

15 MAR 2021 23:59

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

TIMEPOINT

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

19 MAR 2021 11:22:00

Patient Cloud Open Date & Time

18 MAR 2021 00:01

Patient Cloud Close Date & Time

22 MAR 2021 23:59

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

| | |
|---|--|
| TIMEPOINT | DAY 222 |
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Date and time of submission | 29 MAR 2021 14:23:58 |
| Patient Cloud Open Date & Time | 25 MAR 2021 00:01 |
| Patient Cloud Close Date & Time | 29 MAR 2021 23:59 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

| | |
|---|--|
| 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 <input checked="" type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Date and time of submission | 01 APR 2021 10:32:45 |
| Patient Cloud Open Date & Time | 01 APR 2021 00:01 |
| Patient Cloud Close Date & Time | 05 APR 2021 23:59 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

| | |
|---|--|
| TIMEPOINT | DAY 236 |
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Date and time of submission | 11 APR 2021 20:38:53 |
| Patient Cloud Open Date & Time | 08 APR 2021 00:01 |
| Patient Cloud Close Date & Time | 12 APR 2021 23:59 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

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

15 APR 2021 17:39:57

Patient Cloud Open Date & Time

15 APR 2021 00:01

Patient Cloud Close Date & Time

19 APR 2021 23:59

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

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

22 APR 2021 18:20:28

Patient Cloud Open Date & Time

22 APR 2021 00:01

Patient Cloud Close Date & Time

26 APR 2021 23:59

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

TIMEPOINT

DAY 257

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

30 APR 2021 20:46:35

Patient Cloud Open Date & Time

29 APR 2021 00:01

Patient Cloud Close Date & Time

03 MAY 2021 23:59

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

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

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

10 MAY 2021 23:59

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

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

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

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

[Patient Cloud Close Date & Time](#)

17 MAY 2021 23:59

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

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

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

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

[Patient Cloud Close Date & Time](#)

24 MAY 2021 23:59

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

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

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

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

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

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

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

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

[Patient Cloud Close Date & Time](#)

07 JUN 2021 23:59

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

| 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"/> |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

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

[Patient Cloud Close Date & Time](#)

14 JUN 2021 23:59

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

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 ☐

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

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

[Patient Cloud Close Date & Time](#)

21 JUN 2021 23:59

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

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

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JUN 2021 23:59

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

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

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

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

[Patient Cloud Close Date & Time](#)

05 JUL 2021 23:59

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

| TIMEPOINT | DAY 327 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

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

[Patient Cloud Close Date & Time](#)

12 JUL 2021 23:59

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

| 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"/> |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

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

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

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

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

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

[Patient Cloud Close Date & Time](#)

26 JUL 2021 23:59

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

| 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"/> |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

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

[Patient Cloud Close Date & Time](#)

02 AUG 2021 23:59

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

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

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

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

[Patient Cloud Close Date & Time](#)

09 AUG 2021 23:59

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

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 ☐

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

16 AUG 2021 23:59

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

| 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 <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"/> |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

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

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

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 ☐

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

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

[Patient Cloud Close Date & Time](#)

30 AUG 2021 23:59

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

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

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

06 SEP 2021 23:59

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

| TIMEPOINT | DAY 390 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

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

[Patient Cloud Close Date & Time](#)

13 SEP 2021 23:59

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

| TIMEPOINT | DAY 397 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

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

[Patient Cloud Close Date & Time](#)

20 SEP 2021 23:59

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

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

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

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

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

| 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"/> |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

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

[Patient Cloud Close Date & Time](#)

04 OCT 2021 23:59

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

| TIMEPOINT | DAY 418 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

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

[Patient Cloud Close Date & Time](#)

11 OCT 2021 23:59

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

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

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

18 OCT 2021 23:59

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

| TIMEPOINT | DAY 432 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

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

| | |
|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 21 OCT 2021 00:01 |
| Patient Cloud Close Date & Time | 25 OCT 2021 23:59 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

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

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

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

[Patient Cloud Close Date & Time](#)

01 NOV 2021 23:59

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

| 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"/> |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

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

[Patient Cloud Close Date & Time](#)

08 NOV 2021 23:59

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

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 ☐

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

15 NOV 2021 23:59

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

| 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"/> |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

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

[Patient Cloud Close Date & Time](#)

22 NOV 2021 23:59

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

| 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"/> |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

29 NOV 2021 23:59

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

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

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

06 DEC 2021 23:59

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

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

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

13 DEC 2021 23:59

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

| 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"/> |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

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

[Patient Cloud Close Date & Time](#)

20 DEC 2021 23:59

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

| 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"/> |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

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

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

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

| 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 <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"/> |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

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

[Patient Cloud Close Date & Time](#)

03 JAN 2022 23:59

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

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 ☐

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

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

[Patient Cloud Close Date & Time](#)

10 JAN 2022 23:59

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

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

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

17 JAN 2022 23:59

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

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 ☐

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

24 JAN 2022 23:59

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

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

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

31 JAN 2022 23:59

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

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 ☐

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

07 FEB 2022 23:59

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

| TIMEPOINT | DAY 544 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="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"/> |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

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

[Patient Cloud Close Date & Time](#)

14 FEB 2022 23:59

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

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

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

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

[Patient Cloud Close Date & Time](#)

21 FEB 2022 23:59

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

| 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 <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"/> |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

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

[Patient Cloud Close Date & Time](#)

28 FEB 2022 23:59

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

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 ☐

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

07 MAR 2022 23:59

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

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 ☐

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

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

[Patient Cloud Close Date & Time](#)

14 MAR 2022 23:59

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

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 ☐

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

21 MAR 2022 23:59

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

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 ☐

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

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

[Patient Cloud Close Date & Time](#)

28 MAR 2022 23:59

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

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 ☐

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

04 APR 2022 23:59

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

| TIMEPOINT | DAY 600 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

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

[Patient Cloud Close Date & Time](#)

11 APR 2022 23:59

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

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

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

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

[Patient Cloud Close Date & Time](#)

18 APR 2022 23:59

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

| 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"/> |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

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

[Patient Cloud Close Date & Time](#)

25 APR 2022 23:59

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

| 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"/> |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

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

[Patient Cloud Close Date & Time](#)

02 MAY 2022 23:59

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

TIMEPOINT

DAY 628

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

09 MAY 2022 23:59

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

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

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

16 MAY 2022 23:59

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

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

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

23 MAY 2022 23:59

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

| TIMEPOINT | DAY 649 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="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"/> |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

30 MAY 2022 23:59

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

| TIMEPOINT | DAY 656 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="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"/> |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

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

Date and time of submission

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02 JUN 2022 00:01

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06 JUN 2022 23:59

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

| 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 <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"/> |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

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

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

Date and time of submission

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09 JUN 2022 00:01

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13 JUN 2022 23:59

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

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

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

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

Date and time of submission

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16 JUN 2022 00:01

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20 JUN 2022 23:59

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

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 ☐

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

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

Date and time of submission

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23 JUN 2022 00:01

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27 JUN 2022 23:59

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

| 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"/> |

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

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

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04 JUL 2022 23:59

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

| 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"/> |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

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

Date and time of submission

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07 JUL 2022 00:01

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11 JUL 2022 23:59

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

TIMEPOINT

DAY 698

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

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

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

Date and time of submission

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14 JUL 2022 00:01

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18 JUL 2022 23:59

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

TIMEPOINT

DAY 705

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

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

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25 JUL 2022 23:59

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

| TIMEPOINT | DAY 712 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |

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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

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01 AUG 2022 23:59

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

| 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"/> |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

08 AUG 2022 23:59

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

| TIMEPOINT | DAY 726 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

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

| | |
|---|-------------------|
| Patient Cloud Close Date & Time | 15 AUG 2022 23:59 |
|---|-------------------|

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

| 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"/> |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

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

[Patient Cloud Close Date & Time](#)

22 AUG 2022 23:59

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

| 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"/> |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

29 AUG 2022 23:59

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

| 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"/> |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

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

[Patient Cloud Close Date & Time](#)

05 SEP 2022 23:59

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

| 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"/> |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

12 SEP 2022 23:59

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

| 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"/> |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

19 SEP 2022 23:59

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

| 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"/> |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

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

[Patient Cloud Close Date & Time](#)

26 SEP 2022 23:59

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

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 ☐

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

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

[Patient Cloud Close Date & Time](#)

03 OCT 2022 23:59

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

| 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 <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"/> |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

10 OCT 2022 23:59

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

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

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

17 OCT 2022 23:59

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

| 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"/> |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

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

[Patient Cloud Close Date & Time](#)

24 OCT 2022 23:59

US3592229

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 10 Jun 2021 08:21:23

| Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other? | Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache? | Date & Time of Submission |
|---|--|---------------------------|
| No | | 27 FEB 2021 23:00:15 |

US3592229

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 16:55:09

Generated On: 10 Jun 2021 08:21:23

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

9 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3592229

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 16:55:09

Generated On: 10 Jun 2021 08:21:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3592229

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 09:37:55

Generated On: 10 Jun 2021 08:21:23

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3592229

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 09:37:55

Generated On: 10 Jun 2021 08:21:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3592229

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 09:37:55

Generated On: 10 Jun 2021 08:21:23

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 12 JAN 2021

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

Comments

If Contact Not Made, please provide Comments

US3592229

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 09:37:55

Generated On: 10 Jun 2021 08:21:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3592229

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 09:37:55

Generated On: 10 Jun 2021 08:21:23

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 12 FEB 2021

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

Comments

If Contact Not Made, please provide Comments

US3592229

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 09:37:55

Generated On: 10 Jun 2021 08:21:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3592229

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 09:37:55

Generated On: 10 Jun 2021 08:21:23

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

US3592229

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 28 Apr 2021 09:37:55

Generated On: 10 Jun 2021 08:21:23

| | |
|-------------------------------------|---------------------------------------|
| Were vital signs assessed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Date of assessment (dd MMM yyyy) | 19 MAR 2021 |
| Time of assessment (00:00-23:59) | 11:07 (24 HR) |
| Vital Signs Date and Time (derived) | 19 MAR 2021 11:07 |
| Temperature (xxx.x) | 36.9 C |
| Route of measurement | Oral <input checked="" type="radio"/> |
| | Axillary <input type="radio"/> |
| | Other <input type="radio"/> |
| If Other, specify | |
| Pulse (xxx) | 62 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 16 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 159 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 88 mmHg |
| Diastolic Blood Pressure units | MMHG |
| Height (derived) | |
| Weight (derived) | |

US3592229

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 09:37:55

Generated On: 10 Jun 2021 08:21:23

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.

US3592229

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Apr 2021 09:37:55

Generated On: 10 Jun 2021 08:21:23

| | |
|------------------------------------|--------------------------------------|
| Was the sample collected? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Collection date (dd MMM yyyy) | 19 MAR 2021 |
| Collection time (00:00-23:59) | 11:38 (24 HR) |
| Collection date and time (derived) | 19 MAR 2021 11:38 |

US3592229

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 09:37:55

Generated On: 10 Jun 2021 08:21:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3592229

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 09:37:55

Generated On: 10 Jun 2021 08:21:23

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 14 APR 2021

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

Comments

If Contact Not Made, please provide Comments

US3592229

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 09:37:55

Generated On: 10 Jun 2021 08:21:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3592229

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:21:23

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

US3592229

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:21:23

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3592229

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:21:23

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

US3592229

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 10 Jun 2021 08:21:23

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3592229

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

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 09:37:55

Generated On: 10 Jun 2021 08:21:23

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

| | |
|--------------------------|-------------|
| Visit date (dd MMM yyyy) | 25 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 |
|------------|---------------|

US3592229

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

Form: Unblinding

Data signed: (b) (4) 28 Apr 2021 09:37:55

Generated On: 10 Jun 2021 08:21:23

| | |
|---|---|
| Date of updated informed consent (<i>dd MMM yyyy</i>) | 25 JAN 2021 |
| N/A - Subject Unblinded under Amendment 5 and Discontinued from Study | False |
| Was the participant unblinded? | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Under what version of the Protocol was the Participant unblinded? | Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/> |
| Date of unblinding (<i>dd MMM yyyy</i>) | 25 JAN 2021 |
| Participant randomization assignment | mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> |
| Actual Dose 1 | mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/> |
| Actual Dose 2 | mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/> |
| Will participant receive mRNA-1273? | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Placebo Only Flag | 1 |
| Continuing with mRNA-1273 | 1 |

US3592229

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 28 Apr 2021 09:37:55

Generated On: 10 Jun 2021 08:21:23

| | |
|-------------|----------|
| Height | 169.0 cm |
| Weight | 101.8 kg |
| BMI (xxx.x) | 35.64301 |

US3592229

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 28 Apr 2021 09:37:55

Generated On: 10 Jun 2021 08:21:23

| | |
|-------------------------------------|--|
| Height | 169.0 cm |
| Weight | 101.8 kg |
| BMI (xxx.x) | 35.64301 |
| 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) | 25 JAN 2021 |
| Time of assessment (00:00-23:59) | 10:27 (24 HR) |
| Vital Signs Date and Time (derived) | 25 JAN 2021 10:27 |
| Temperature (xxx.x) | 36.8 C |
| Route of measurement | Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/> |
| If Other, specify | |
| Pulse (xxx) | 100 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 16 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 142 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 101 mmHg |
| Diastolic Blood Pressure units | MMHG |

US3592229

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 28 Apr 2021 09:37:55

Generated On: 10 Jun 2021 08:21:23

| | |
|-------------------------------------|--|
| Height | 169.0 cm |
| Weight | 101.8 kg |
| BMI (xxx.x) | 35.64301 |
| Timepoint | Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/> |
| Were vital signs assessed? | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Date of assessment (dd MMM yyyy) | 25 JAN 2021 |
| Time of assessment (00:00-23:59) | 11:20 (24 HR) |
| Vital Signs Date and Time (derived) | 25 JAN 2021 11:20 |
| Temperature (xxx.x) | 98.5 F |
| Route of measurement | Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/> |
| If Other, specify | |
| Pulse (xxx) | 95 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 16 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 145 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 98 mmHg |
| Diastolic Blood Pressure units | MMHG |

US3592229

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

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 09:37:55

Generated On: 10 Jun 2021 08:21:23

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

25 JAN 2021

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

US3592229

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

Form: Exposure

Data signed: (b) (4) 28 Apr 2021 09:37:55

Generated On: 10 Jun 2021 08:21:23

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

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

What was the treatment date? (dd MMM yyyy) 25 JAN 2021

What was the treatment time? (00:00-23:59) 10:48 (24 HR)

Treatment Date and Time (derived) 25 JAN 2021 10:48

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

US3592229

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Apr 2021 09:37:55

Generated On: 10 Jun 2021 08:21:23

| | |
|------------------------------------|--------------------------------------|
| Was the sample collected? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Collection date (dd MMM yyyy) | 25 JAN 2021 |
| Collection time (00:00-23:59) | 10:40 (24 HR) |
| Collection date and time (derived) | 25 JAN 2021 10:40 |

US3592229

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 28 Apr 2021 09:37:55

Generated On: 10 Jun 2021 08:21:23

| | |
|------------------------------------|--------------------------------------|
| Was the sample collected? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Collection date (dd MMM yyyy) | 25 JAN 2021 |
| Collection time (00:00 - 23:59) | 10:30 |
| Collection Date and Time (derived) | 25 JAN 2021 10:30 |

US3592229

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

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 09:37:55

Generated On: 10 Jun 2021 08:21:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3592229

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 09:37:55

Generated On: 10 Jun 2021 08:21:23

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 2 FEB 2021

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

Comments

If Contact Not Made, please provide Comments

US3592229

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 09:37:55

Generated On: 10 Jun 2021 08:21:23

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

US3592229

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 09:35:59

Generated On: 10 Jun 2021 08:21:23

| | |
|---|---|
| Was this visit performed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Visit date (dd MMM yyyy) | 23 FEB 2021 |
| Was visit performed at the participant's home or at the clinic? | Home <input type="radio"/> |
| | Clinic <input checked="" type="radio"/> |
| Folder OID | OLD29 |

US3592229

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 28 Apr 2021 09:35:59

Generated On: 10 Jun 2021 08:21:23

| | |
|-------------------------------------|---|
| 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) | 23 FEB 2021 |
| Time of assessment (00:00-23:59) | 13:14 (24 HR) |
| Vital Signs Date and Time (derived) | 23 FEB 2021 13:14 |
| Temperature (xxx.x) | 36.9 C |
| Route of measurement | Oral <input checked="" type="radio"/> |
| | Axillary <input type="radio"/> |
| | Other <input type="radio"/> |
| If Other, specify | |
| Pulse (xxx) | 73 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 12 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 142 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 90 mmHg |
| Diastolic Blood Pressure units | MMHG |

US3592229

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 28 Apr 2021 09:35:59

Generated On: 10 Jun 2021 08:21:23

| | |
|-------------------------------------|--|
| Timepoint | Pre-Dose <input type="radio"/> |
| | Post-Dose <input checked="" type="radio"/> |
| Were vital signs assessed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Date of assessment (dd MMM yyyy) | 23 FEB 2021 |
| Time of assessment (00:00-23:59) | 14:11 (24 HR) |
| Vital Signs Date and Time (derived) | 23 FEB 2021 14:11 |
| Temperature (xxx.x) | 98.4 F |
| Route of measurement | Oral <input checked="" type="radio"/> |
| | Axillary <input type="radio"/> |
| | Other <input type="radio"/> |
| If Other, specify | |
| Pulse (xxx) | 80 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 16 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 135 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 95 mmHg |
| Diastolic Blood Pressure units | MMHG |

US3592229

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 09:35:59

Generated On: 10 Jun 2021 08:21:23

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

23 FEB 2021

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

US3592229

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 28 Apr 2021 09:35:59

Generated On: 10 Jun 2021 08:21:23

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

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

What was the treatment date? (dd MMM yyyy) 23 FEB 2021

What was the treatment time? (00:00-23:59) 13:39 (24 HR)

Treatment Date and Time (derived) 23 FEB 2021 13:39

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

What was the frequency of the study treatment dosing? ONCE

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

US3592229

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 09:35:59

Generated On: 10 Jun 2021 08:21:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3592229

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 09:37:55

Generated On: 10 Jun 2021 08:21:23

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

2 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3592229

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 09:37:55

Generated On: 10 Jun 2021 08:21:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3592229

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 09:36:00

Generated On: 10 Jun 2021 08:21:23

| | |
|---|---|
| Was this visit performed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Visit date (dd MMM yyyy) | 19 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 | OLD57 |

US3592229

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 28 Apr 2021 09:36:00

Generated On: 10 Jun 2021 08:21:23

| | |
|-------------------------------------|---------------------------------------|
| Were vital signs assessed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Date of assessment (dd MMM yyyy) | 19 MAR 2021 |
| Time of assessment (00:00-23:59) | 11:07 (24 HR) |
| Vital Signs Date and Time (derived) | 19 MAR 2021 11:07 |
| Temperature (xxx.x) | 36.9 C |
| Route of measurement | Oral <input checked="" type="radio"/> |
| | Axillary <input type="radio"/> |
| | Other <input type="radio"/> |
| If Other, specify | |
| Pulse (xxx) | 62 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 16 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 159 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 88 mmHg |
| Diastolic Blood Pressure units | MMHG |
| Height (derived) | |
| Weight (derived) | |

US3592229

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 09:36:00

Generated On: 10 Jun 2021 08:21:23

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Apr 2021 09:36:00

Generated On: 10 Jun 2021 08:21:23

| | |
|------------------------------------|--------------------------------------|
| Was the sample collected? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Collection date (dd MMM yyyy) | 19 MAR 2021 |
| Collection time (00:00-23:59) | 11:38 (24 HR) |
| Collection date and time (derived) | 19 MAR 2021 11:38 |

US3592229

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 16 Apr 2021 15:55:47

Generated On: 10 Jun 2021 08:21:23

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 30 Apr 2021 15:49:10

Generated On: 10 Jun 2021 08:21:23

AEID

Adverse event

URINARY TRACT INFECTION

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)

22 AUG 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

26 AUG 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 30 Apr 2021 15:49:10

Generated On: 10 Jun 2021 08:21:23

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

US3592229

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 30 Apr 2021 15:49:10

Generated On: 10 Jun 2021 08:21:23

| | |
|--|--|
| AEID | USA-US103-2021-MRNA-1273-P30 1000006 |
| Adverse event | ATYPICAL COMPLEX HYPERPLASIA |
| Was this a medically-attended AE? | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Was this a Solicited Adverse Reaction? | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Is this event a confirmed diagnosis of Symptomatic Covid-19? | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Start date (dd MMM yyyy) | 19 NOV 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) | 16 MAR 2021 |
| End time (00:00-23:59) | |
| AE End Date and Time (derived) | |
| Severity | Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/> |
| Is the adverse event serious? | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| AE is serious due To (check all that apply) | |
| Death | False |
| Life threatening | False |
| Requires inpatient or prolongation of existing Hospitalization | True |
| Hospital Admission Date (dd MMM yyyy) | 16 MAR 2021 |
| Hospital Discharge Date (dd MMM yyyy) | 17 MAR 2021 |
| Admitted to ICU? | Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/> |
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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 30 Apr 2021 15:49:10

Generated On: 10 Jun 2021 08:21:23

| | |
|--|---|
| Number of Days in ICU | |
| Persistent or significant disability or incapacity | False |
| Congenital anomaly or birth defect | False |
| Other medically important event | False |
| Relationship to investigational product | Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/> |
| Relationship to Study Procedure | Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/> |
| Action taken with investigational product | None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/> |
| Other action taken (check all that apply) | |
| None | False |
| Concomitant Medication | True |
| Concomitant Procedure | 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 | |

US3592229

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 30 Apr 2021 15:49:10

Generated On: 10 Jun 2021 08:21:23

SUBJECT WAS DIAGNOSED
WITH AN ATYPICAL COMPLEX
HYPERPLASIA IN NOVEMBER
DURING WELL WOMAN EXAM.
SUBJECT HAD HYSTERECTOMY
TO RESOLVE ATYPICAL
COMPLEX HYPERPLASIA AND
STAYED OVERNIGHT IN
HOSPITAL ON 03/16/2021. WILL
UPDATED AS MEDICAL
RECORDS AND INFORMATION
BECOMES AVAILABLE.

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

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 03 May 2021 19:54:33

Generated On: 10 Jun 2021 08:21:23

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

Yes ☒

No ☐

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

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 30 Apr 2021 15:49:10

Generated On: 10 Jun 2021 08:21:23

Name of Medication PAROXETINE

Prophylaxis Yes ☐
No ☒

Indication DEPRESSION

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 (1)

Data signed: (b) (4) 30 Apr 2021 15:49:10

Generated On: 10 Jun 2021 08:21:23

| | | |
|--|--------------------------|----------------------------------|
| | 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 JAN 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 (2)

Data signed: (b) (4) 30 Apr 2021 15:49:10

Generated On: 10 Jun 2021 08:21:23

Name of Medication PANTOPRAZOLE

Prophylaxis Yes ☐
No ☒

Indication GASTROESOPHAGEAL REFLUX
DISEASE

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 30 Apr 2021 15:49:10

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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) | UN MAR 2018 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input checked="" type="radio"/> |
| | No | <input type="radio"/> |
| If not Ongoing, End date (dd MMM yyyy) | | |
| Was this medication taken for solicited event? | Yes | <input type="radio"/> |
| | No | <input checked="" type="radio"/> |
| Separate Dosage Number (derived) | 2 | |
| Interval Dosage Unit Number (derived) | 1 | |
| Interval Dosage Definition (derived) | 802 | <input type="radio"/> |
| | 803 | <input type="radio"/> |
| | 804 | <input checked="" type="radio"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 30 Apr 2021 15:49:10

Generated On: 10 Jun 2021 08:21:23

Name of Medication D-AMPHETAMINE ER

Prophylaxis Yes ☐
No ☒

Indication ATTENTION DEFICIENCY
DISORDER

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 30 Apr 2021 15:49:10

Generated On: 10 Jun 2021 08:21:23

| | | |
|--|--------------------------|----------------------------------|
| | 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) | UN MAR 2014 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input checked="" type="radio"/> |
| | No | <input type="radio"/> |
| If not Ongoing, End date (dd MMM yyyy) _____ | | |
| Was this medication taken for solicited event? | Yes | <input type="radio"/> |
| | No | <input checked="" type="radio"/> |
| Separate Dosage Number (derived) | 1 | |
| Interval Dosage Unit Number (derived) | 1 | |
| Interval Dosage Definition (derived) | 802 | <input type="radio"/> |
| | 803 | <input type="radio"/> |
| | 804 | <input checked="" type="radio"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 30 Apr 2021 15:49:10

Generated On: 10 Jun 2021 08:21:23

Name of Medication AMPHETAMINE

Prophylaxis Yes ☐
No ☒

Indication ATTENTION DEFICIENCY
DISORDER

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 30 Apr 2021 15:49:10

Generated On: 10 Jun 2021 08:21:23

| | | |
|--|--------------------------|----------------------------------|
| | 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) | UN MAR 2014 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input checked="" type="radio"/> |
| | No | <input type="radio"/> |
| If not Ongoing, End date (dd MMM yyyy) | | |
| Was this medication taken for solicited event? | Yes | <input type="radio"/> |
| | No | <input checked="" type="radio"/> |
| Separate Dosage Number (derived) | 1 | |
| Interval Dosage Unit Number (derived) | 1 | |
| Interval Dosage Definition (derived) | 802 | <input type="radio"/> |
| | 803 | <input type="radio"/> |
| | 804 | <input checked="" type="radio"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 30 Apr 2021 15:49:10

Generated On: 10 Jun 2021 08:21:23

Name of Medication SIMVASTATIN

Prophylaxis Yes ☐
No ☒

Indication HYPERCHOLESTEROLEMIA

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) 30 Apr 2021 15:49:10

Generated On: 10 Jun 2021 08:21:23

| | | |
|--|--------------------------|----------------------------------|
| | 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 JAN 2014 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input checked="" type="radio"/> |
| | No | <input type="radio"/> |
| If not Ongoing, End date (dd MMM yyyy) _____ | | |
| Was this medication taken for solicited event? | Yes | <input type="radio"/> |
| | No | <input checked="" type="radio"/> |
| Separate Dosage Number (derived) | 1 | |
| Interval Dosage Unit Number (derived) | 1 | |
| Interval Dosage Definition (derived) | 802 | <input type="radio"/> |
| | 803 | <input type="radio"/> |
| | 804 | <input checked="" type="radio"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 30 Apr 2021 15:49:10

Generated On: 10 Jun 2021 08:21:23

Name of Medication IRBESARTAN
HYDROCHLOROTHIAZIDE

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 150/12.5

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 30 Apr 2021 15:49:10

Generated On: 10 Jun 2021 08:21:23

| | | |
|--|--------------------------|-------------------------------------|
| | 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) | UN JAN 2017 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy) | 05 NOV 2020 | |
| Was this medication taken for solicited event? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| Separate Dosage Number (derived) | 1 | |
| Interval Dosage Unit Number (derived) | 1 | |
| Interval Dosage Definition (derived) | 802 | <input type="checkbox"/> |
| | 803 | <input type="checkbox"/> |
| | 804 | <input checked="" type="checkbox"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 30 Apr 2021 15:49:10

Generated On: 10 Jun 2021 08:21:23

Name of Medication IBUPROFEN

Prophylaxis Yes ☐
No ☒

Indication PAIN, FEVER

Dose per administration 400

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 30 Apr 2021 15:49:10

Generated On: 10 Jun 2021 08:21:23

| | | |
|--|--------------------------|-------------------------------------|
| | 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 AUG 2020 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy) 22 AUG 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"/> |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 30 Apr 2021 15:49:10

Generated On: 10 Jun 2021 08:21:23

Name of Medication NITROFURANTOIN

Prophylaxis Yes ☐
No ☒

Indication URINARY TRACT INFECTION

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 30 Apr 2021 15:49:10

Generated On: 10 Jun 2021 08:21:23

| | | |
|--|--------------------------------------|--------------------------|
| | 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 AUG 2020 | |
| Start date completely unknown | False | |
| Ongoing? | Yes <input type="checkbox"/> | |
| | No <input checked="" type="radio"/> | |
| If not Ongoing, End date (dd MMM yyyy) | 26 AUG 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"/> | |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 30 Apr 2021 15:49:10

Generated On: 10 Jun 2021 08:21:23

Name of Medication IRBESARTAN/HCTZ

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 30 Apr 2021 15:49:10

Generated On: 10 Jun 2021 08:21:23

| | | |
|--|--------------------------|----------------------------------|
| | 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) | 6 NOV 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) | 2 | |
| Interval Dosage Unit Number (derived) | 1 | |
| Interval Dosage Definition (derived) | 802 | <input type="radio"/> |
| | 803 | <input type="radio"/> |
| | 804 | <input checked="" type="radio"/> |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 30 Apr 2021 15:49:10

Generated On: 10 Jun 2021 08:21:23

Name of Medication INFLUENZA VACCINE

Prophylaxis Yes ☒
No ☐

Indication INFLUENZA PROPHYLAXIS

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 30 Apr 2021 15:49:10

Generated On: 10 Jun 2021 08:21:23

| | | |
|--|--------------------------|----------------------------------|
| | Intramuscular | <input checked="" type="radio"/> |
| | Respiratory (Inhalation) | <input type="radio"/> |
| | Intralesional | <input type="radio"/> |
| | Intraperitoneal | <input type="radio"/> |
| | Nasal | <input type="radio"/> |
| | Vaginal | <input type="radio"/> |
| | Rectal | <input type="radio"/> |
| | Intravenous | <input type="radio"/> |
| | Intravenous Bolus | <input type="radio"/> |
| | Intravenous Drip | <input type="radio"/> |
| | Other | <input type="radio"/> |
| If route of administration is Other, specify _____ | | |
| Start date (dd MMM yyyy) | | 15 OCT 2020 |
| Start date completely unknown | | False |
| Ongoing? | Yes | <input type="radio"/> |
| | No | <input checked="" type="radio"/> |
| If not Ongoing, End date (dd MMM yyyy) | | 15 OCT 2020 |
| Was this medication taken for solicited event? | Yes | <input type="radio"/> |
| | No | <input checked="" type="radio"/> |
| Separate Dosage Number (derived) _____ | | |
| Interval Dosage Unit Number (derived) _____ | | |
| Interval Dosage Definition (derived) | 802 | <input type="radio"/> |
| | 803 | <input type="radio"/> |
| | 804 | <input type="radio"/> |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 30 Apr 2021 15:49:10

Generated On: 10 Jun 2021 08:21:23

Name of Medication NORCO [HYDROCODONE
5MG/ACETAMINOPHEN325MG]

Prophylaxis Yes ☐
No ☒

Indication ATYPICAL COMPLEX
HYPERPLASIA

Dose per administration 5/325

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 30 Apr 2021 15:49:10

Generated On: 10 Jun 2021 08:21:23

| | | |
|--|--------------------------|-------------------------------------|
| | 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) | 16 MAR 2021 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy) | | 18 MAR 2021 |
| Was this medication taken for solicited event? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| Separate Dosage Number (derived) _____ | | |
| Interval Dosage Unit Number (derived) _____ | | |
| Interval Dosage Definition (derived) | 802 | <input type="checkbox"/> |
| | 803 | <input type="checkbox"/> |
| | 804 | <input type="checkbox"/> |

US3592229

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 03 May 2021 19:54:33

Generated On: 10 Jun 2021 08:21:23

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3592229

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 30 Apr 2021 15:49:10

Generated On: 10 Jun 2021 08:21:23

| Procedure/Surgery date (dd MMM yyyy) | Procedure/Surgery | Indication | If indication is Other, specify |
|---|-------------------|---------------|---------------------------------|
| 16 MAR 2021 | HYSTERECTOMY | Adverse Event | |

US3592229

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 08:21:23

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

US3592229

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 08:21:23

Date of study discontinuation/completion (dd MMM yyyy)

Reason for discontinuation

AE (specify) ☐

SAE (specify) ☐

Complete ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Other ☐

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

If reason for discontinuation is Death, main cause of death

Adverse event ☐

Unknown ☐

Other ☐

If main cause of death is Other, specify

Date of death (dd MMM yyyy)

Was autopsy performed?

Yes ☐

No ☐

Unknown ☐

US3592229

Folder: SAE USA-US103-2021-MRNA-1273-P301000006

Form: Safety Report Form

Data signed: (b) (4) 03 May 2021 19:54:33

Generated On: 10 Jun 2021 08:21:23

| | |
|--|--|
| SAEID | USA-US103-2021-MRNA-1273-P301000006 |
| 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 | TERRY |
| Investigator's Last Name | POLING |
| Site Address: Street | 1709 S ROCK RD |
| Site Address: City | WICHITA |
| Site Address: State | KS |
| Site Address: Postal Code | 67207 |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 2 |

US3592229

Folder: SAE USA-US103-2021-MRNA-1273-P301000006

Form: Safety Report Form (1)

Data signed: (b) (4) 03 May 2021 19:54:33

Generated On: 10 Jun 2021 08:21:23

| | |
|---|--|
| SAEID | USA-US103-2021-MRNA-1273-P301000006 |
| 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 | TERRY |
| Investigator's Last Name | POLING |
| Site Address: Street | 1709 S ROCK RD |
| Site Address: City | WICHITA |
| Site Address: State | KS |
| Site Address: Postal Code | 67207 |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 2 |
| Date of submission (Pre-filled from custom function) | 22/MAR/2021 11:07 |
| Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge. | True |

US3592229

Folder: SAE USA-US103-2021-MRNA-1273-P301000006

Form: Safety Report Form (2)

Data signed: (b) (4) 03 May 2021 19:54:33

Generated On: 10 Jun 2021 08:21:23

| | |
|---|--|
| SAEID | USA-US103-2021-MRNA-1273-P301000006 |
| 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 | TERRY |
| Investigator's Last Name | POLING |
| Site Address: Street | 1709 S ROCK RD |
| Site Address: City | WICHITA |
| Site Address: State | KS |
| Site Address: Postal Code | 67207 |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 2 |
| Date of submission (Pre-filled from custom function) | 30/APR/2021 12:27 |
| 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

US3592229 (Prod: Alliance for Multispecialty Research, LLC - East Wichita)

US3592229

Form: Participant Creation

Generated On: 10 Jun 2021 08:21:23

[Participant ID](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:36:00 |
| User entered 'US3592229' | (b) (4) RWS_ENDPOINT ENDPOINT (b) (4) | 18 Aug 2020 22:14:20 |

US3592229

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:21:23

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:30:20 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 18 Aug 2020 23:29:47 |

US3592229

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:30:20 |
| User entered '18 AUG 2020' | (b) (4) RWS_ENDPOINT ENDPOINT (b) (4) | 18 Aug 2020 22:14:21 |

US3592229

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|--------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:30:20 |
| User entered 'Clinic (Clinic)' | (b) (4) (b) (4), (b) (6) | 18 Aug 2020 23:29:47 |

US3592229

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:21:23

[Folder OID](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |
| User entered 'SCRN' | System | 18 Aug 2020 23:29:47 |

US3592229

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:21:23

Date of Birth (MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:30:20 |
| User entered (b) (6) 1967' | (b) (4) RWS_ENDPOINT ENDPOINT (b) (4) | 18 Aug 2020 22:14:22 |

US3592229

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:21:23

[Age](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:30:20 |
| User entered '52' | (b) (4) (b) (4), (b) (6) | 18 Aug 2020 23:30:08 |

US3592229

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:21:23

[Age Units](#)

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |
| User entered 'YEARS' | System | 18 Aug 2020 23:30:08 |

US3592229

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:21:23

[Age \(Derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |
| User entered '52' | System | 18 Aug 2020 23:30:30 |

US3592229

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:21:23

[Sex](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:30:20 |
| User entered 'Female (F)' | (b) (4) (b) (4), (b) (6) | 18 Aug 2020 23:30:08 |

US3592229

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:21:23

[Ethnicity](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:30:20 |
| User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)' | (b) (4) (b) (4), (b) (6) | 18 Aug 2020 23:30:08 |

US3592229

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:21:23

White

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:30:20 |
| User entered 'l' | (b) (4) (b) (4), (b) (6) | 18 Aug 2020 23:30:08 |

US3592229

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:21:23

[Black](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:30:20 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 18 Aug 2020 23:30:08 |

US3592229

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:21:23

[Asian](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:30:20 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 18 Aug 2020 23:30:08 |

US3592229

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:21:23

[American Indian or Alaska Native](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:30:20 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 18 Aug 2020 23:30:08 |

US3592229

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:21:23

[Native Hawaiian or other Pacific Islander](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:30:20 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 18 Aug 2020 23:30:08 |

US3592229

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:21:23

[Other](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:30:20 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 18 Aug 2020 23:30:08 |

US3592229

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:21:23

If race is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:30:20 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 18 Aug 2020 23:30:08 |

US3592229

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:21:23

Unknown

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:30:20 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 18 Aug 2020 23:30:08 |

US3592229

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:21:23

[Not reported](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:30:20 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 18 Aug 2020 23:30:08 |

US3592229

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:21:23

Date of Informed Consent (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:30:20 |
| User entered '18 Aug 2020' | (b) (4) (b) (4), (b) (6) | 18 Aug 2020 23:30:30 |

US3592229

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |
| User entered 'Aug 2020' | System | 18 Aug 2020 23:30:30 |

US3592229

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |
| User entered '2020' | System | 18 Aug 2020 23:30:30 |

US3592229

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:21:23

[Protocol Version](#)

| Audit | User | Time (GMT) |
|--------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:30:20 |
| User entered 'Amendment 2 (2)' | (b) (4) (b) (4), (b) (6) | 18 Aug 2020 23:30:30 |

US3592229

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:30:20 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 18 Aug 2020 23:30:30 |

US3592229

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:21:23

If No, indicate reason for screen fail

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:30:20 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 18 Aug 2020 23:30:30 |

US3592229

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:21:23

If reason for screen fail is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:30:20 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 18 Aug 2020 23:30:30 |

US3592229

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:21:23

[Was this participant screened previously?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:30:20 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 18 Aug 2020 23:30:30 |

US3592229

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:21:23

[If Yes, previous participant number](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:30:20 |
| User entered empty. | (b) (4) RWS_ENDPOINT ENDPOINT (b) (4) | 18 Aug 2020 22:14:21 |

US3592229

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:21:23

[Enrollment Trigger](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |
| User entered 'l' | System | 18 Aug 2020 23:30:36 |

US3592229

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:30:20 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 18 Aug 2020 23:30:36 |

US3592229

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 08:21:23

[Were any significant conditions reported?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:30:20 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 19 Aug 2020 22:38:45 |

US3592229

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:21:23

Condition

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:30:20 |
| User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Upper respiratory tract disorders (excl infections), HLT: Nasal congestion and inflammations, PT: Rhinitis allergic, LLT: Allergic rhinitis - version MedDRA\23.0. | Coder Import (b) (4) | 19 Aug 2020 22:40:07 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0. | Coder Import (b) (4) | 19 Aug 2020 22:40:07 |
| Data point term sent to Coder | System | 19 Aug 2020 22:39:54 |
| User entered 'allergic RHINITIS' reason for change: | (b) (4), (b) (6) | 19 Aug 2020 22:39:51 |
| Data Entry Error | | |
| Data point term sent to Coder | System | 19 Aug 2020 22:39:51 |
| User entered 'rhinitis' | (b) (4), (b) (6) | 19 Aug 2020 22:39:31 |

US3592229

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:30:20 |
| User entered 'un Mar 1988' | (b) (4) (b) (4), (b) (6) | 19 Aug 2020 22:39:31 |

US3592229

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:21:23

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:30:20 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 19 Aug 2020 22:39:31 |

US3592229

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:21:23

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:30:20 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 19 Aug 2020 22:39:31 |

US3592229

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:30:20 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 19 Aug 2020 22:39:31 |

US3592229

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:21:23

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:30:20 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 19 Aug 2020 22:39:31 |

US3592229

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |
| User entered 'Mar 1988' | System | 19 Aug 2020 22:39:31 |

US3592229

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:21:23

Start Year (derived)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |
| User entered '1988' | System | 19 Aug 2020 22:39:31 |

US3592229

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |
| User entered empty. | System | 19 Aug 2020 22:39:31 |

US3592229

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |
| User entered empty. | System | 19 Aug 2020 22:39:31 |

US3592229

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:21:23

[Condition](#)

| Audit | User | Time (GMT) |
|---|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:30:20 |
| 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) | 19 Aug 2020 22:42:12 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 19 Aug 2020 22:42:12 |
| Data point term sent to Coder | System | 19 Aug 2020 22:40:54 |
| User entered 'hypertension' | (b) (4), (b) (6) | 19 Aug 2020 22:40:26 |

US3592229

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:30:20 |
| User entered 'un Mar 1988' | (b) (4) (b) (4), (b) (6) | 19 Aug 2020 22:40:26 |

US3592229

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:21:23

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:30:20 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 19 Aug 2020 22:40:26 |

US3592229

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:21:23

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:30:20 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 19 Aug 2020 22:40:26 |

US3592229

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:30:20 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 19 Aug 2020 22:40:26 |

US3592229

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:21:23

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:30:20 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 19 Aug 2020 22:40:26 |

US3592229

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |
| User entered 'Mar 1988' | System | 19 Aug 2020 22:40:26 |

US3592229

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |
| User entered '1988' | System | 19 Aug 2020 22:40:26 |

US3592229

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |
| User entered empty. | System | 19 Aug 2020 22:40:26 |

US3592229

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |
| User entered empty. | System | 19 Aug 2020 22:40:26 |

US3592229

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:21:23

[Condition](#)

| Audit | User | Time (GMT) |
|--|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:30:20 |
| 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) | 19 Aug 2020 22:42:12 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0. | Coder Import (b) (4) (b) (4) | 19 Aug 2020 22:42:12 |
| Data point term sent to Coder | System | 19 Aug 2020 22:41:55 |
| User entered 'hypercholesterolemia' | (b) (4), (b) (6) | 19 Aug 2020 22:41:11 |

US3592229

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:30:20 |
| User entered 'un Jan 2008' | (b) (4) (b) (4), (b) (6) | 19 Aug 2020 22:41:11 |

US3592229

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:21:23

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:30:20 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 19 Aug 2020 22:41:11 |

US3592229

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:21:23

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:30:20 |
| User closed query 'Data is required. Please complete.' (Site from System). | (b) (4) | 19 Aug 2020 22:41:58 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 19 Aug 2020 22:41:58 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | (b) (4), (b) (6) | 19 Aug 2020 22:41:58 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 19 Aug 2020 22:41:11 |
| User entered empty. | (b) (4), (b) (6) | 19 Aug 2020 22:41:11 |

US3592229

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:30:20 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 19 Aug 2020 22:41:11 |

US3592229

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:21:23

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:30:20 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 19 Aug 2020 22:41:11 |

US3592229

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |
| User entered 'Jan 2008' | System | 19 Aug 2020 22:41:11 |

US3592229

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:21:23

Start Year (derived)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |
| User entered '2008' | System | 19 Aug 2020 22:41:11 |

US3592229

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |
| User entered empty. | System | 19 Aug 2020 22:41:11 |

US3592229

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |
| User entered empty. | System | 19 Aug 2020 22:41:11 |

US3592229

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:21:23

[Condition](#)

| Audit | User | Time (GMT) |
|--|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:30:20 |
| User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastroesophageal reflux disease, LLT: Gastroesophageal reflux disease - version MedDRA\\23.0. | (b) (4) Coder Import (b) (4) (b) (4) | 19 Aug 2020 22:47:08 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 19 Aug 2020 22:47:08 |
| Data point term sent to Coder | System | 19 Aug 2020 22:46:05 |
| User entered 'gastroesophageal reflux disease' | (b) (4), (b) (6) | 19 Aug 2020 22:45:36 |

US3592229

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:30:20 |
| User entered 'un Mar 2014' | (b) (4) (b) (4), (b) (6) | 19 Aug 2020 22:45:36 |

US3592229

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:21:23

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:30:20 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 19 Aug 2020 22:45:36 |

US3592229

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:21:23

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:30:20 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 19 Aug 2020 22:45:36 |

US3592229

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:30:20 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 19 Aug 2020 22:45:36 |

US3592229

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:21:23

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:30:20 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 19 Aug 2020 22:45:36 |

US3592229

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |
| User entered 'Mar 2014' | System | 19 Aug 2020 22:45:36 |

US3592229

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:21:23

Start Year (derived)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |
| User entered '2014' | System | 19 Aug 2020 22:45:36 |

US3592229

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |
| User entered empty. | System | 19 Aug 2020 22:45:36 |

US3592229

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |
| User entered empty. | System | 19 Aug 2020 22:45:36 |

US3592229

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:21:23

[Condition](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:30:20 |
| User coded data point as SOC: Social circumstances, HLT: Age related factors, HLT: Age related issues, PT: Postmenopause, LLT: Postmenopause - version MedDRA\\23.0. | (b) (4) Coder Import (b) (4) | 19 Aug 2020 22:48:09 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 19 Aug 2020 22:48:09 |
| Data point term sent to Coder | System | 19 Aug 2020 22:47:05 |
| User entered 'postmenopausal' | (b) (4), (b) (6) | 19 Aug 2020 22:46:18 |

US3592229

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:21:23

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:30:20 |
| User closed query 'Per DM CLR: Please note, Start date of MH = UN UNK 1990. However, there is no Post-menopausal date recorded in Childbearing eCRF. Review and reconcile dates as appropriate. Else, clarify. ' (Site from DM). | (b) (4) (b) (4), (b) (6) | 06 Oct 2020 07:18:08 |
| Query 'Per DM CLR: Please note, Start date of MH = UN UNK 1990. However, there is no Post-menopausal date recorded in Childbearing eCRF. Review and reconcile dates as appropriate. Else, clarify. ' answered with 'date has been entered' (Site from DM). | (b) (4), (b) (6) | 01 Oct 2020 21:04:37 |
| User opened query 'Per DM CLR: Please note, Start date of MH = UN UNK 1990. However, there is no Post-menopausal date recorded in Childbearing eCRF. Review and reconcile dates as appropriate. Else, clarify. ' (Site from DM). | (b) (4), (b) (6) | 28 Sep 2020 08:10:35 |
| User entered 'un Jan 2018' | (b) (4), (b) (6) | 19 Aug 2020 22:46:18 |

US3592229

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:21:23

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:30:20 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 19 Aug 2020 22:46:18 |

US3592229

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:21:23

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:30:20 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 19 Aug 2020 22:46:18 |

US3592229

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:30:20 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 19 Aug 2020 22:46:18 |

US3592229

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:21:23

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:30:20 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 19 Aug 2020 22:46:18 |

US3592229

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |
| User entered 'Jan 2018' | System | 19 Aug 2020 22:46:18 |

US3592229

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:21:23

Start Year (derived)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |
| User entered '2018' | System | 19 Aug 2020 22:46:18 |

US3592229

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |
| User entered empty. | System | 19 Aug 2020 22:46:18 |

US3592229

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |
| User entered empty. | System | 19 Aug 2020 22:46:18 |

US3592229

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:21:23

[Condition](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:30:20 |
| User coded data point as SOC: Psychiatric disorders, HLGT: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression - version MedDRA\\23.0. | (b) (4) Coder Import (b) (4) | 19 Aug 2020 22:48:09 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 19 Aug 2020 22:48:09 |
| Data point term sent to Coder | System | 19 Aug 2020 22:47:07 |
| User entered 'depression' | (b) (4), (b) (6) | 19 Aug 2020 22:46:56 |

US3592229

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:30:20 |
| User entered 'un Mar 2016' | (b) (4) (b) (4), (b) (6) | 19 Aug 2020 22:46:56 |

US3592229

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:21:23

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:30:20 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 19 Aug 2020 22:46:56 |

US3592229

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:21:23

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:30:20 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 19 Aug 2020 22:46:56 |

US3592229

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:30:20 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 19 Aug 2020 22:46:56 |

US3592229

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:21:23

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:30:20 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 19 Aug 2020 22:46:56 |

US3592229

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |
| User entered 'Mar 2016' | System | 19 Aug 2020 22:46:56 |

US3592229

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |
| User entered '2016' | System | 19 Aug 2020 22:46:56 |

US3592229

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |
| User entered empty. | System | 19 Aug 2020 22:46:56 |

US3592229

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |
| User entered empty. | System | 19 Aug 2020 22:46:56 |

US3592229

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:21:23

[Condition](#)

| Audit | User | Time (GMT) |
|---|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:30:20 |
| User coded data point as SOC: Psychiatric disorders, HLTG: Sleep disorders and disturbances, HLT: Disturbances in initiating and maintaining sleep, PT: Insomnia, LLT: Insomnia - version MedDRA\\23.0. | Coder Import (b) (4) | 19 Aug 2020 22:49:10 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 19 Aug 2020 22:49:10 |
| Data point term sent to Coder | System | 19 Aug 2020 22:48:08 |
| User entered 'insomnia' | (b) (4), (b) (6) | 19 Aug 2020 22:47:26 |

US3592229

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:30:20 |
| User entered 'un Mar 2016' | (b) (4) (b) (4), (b) (6) | 19 Aug 2020 22:47:26 |

US3592229

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:21:23

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:30:20 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 19 Aug 2020 22:47:26 |

US3592229

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:21:23

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:30:20 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 19 Aug 2020 22:47:26 |

US3592229

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:30:20 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 19 Aug 2020 22:47:26 |

US3592229

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:21:23

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:30:20 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 19 Aug 2020 22:47:26 |

US3592229

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |
| User entered 'Mar 2016' | System | 19 Aug 2020 22:47:26 |

US3592229

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:21:23

Start Year (derived)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |
| User entered '2016' | System | 19 Aug 2020 22:47:26 |

US3592229

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |
| User entered empty. | System | 19 Aug 2020 22:47:26 |

US3592229

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |
| User entered empty. | System | 19 Aug 2020 22:47:26 |

US3592229

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:21:23

Condition

| Audit | User | Time (GMT) |
|---|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:30:20 |
| User coded data point as SOC: Psychiatric disorders, HLG: Cognitive and attention disorders and disturbances, HLT: Attention deficit and disruptive behaviour disorders, PT: Attention deficit hyperactivity disorder, LLT: Attention deficit disorder - version MedDRA\23.0. | (b) (4) Coder Import (b) (4) | 19 Aug 2020 23:57:52 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0. | Coder Import (b) (4) (b) (4) | 19 Aug 2020 23:57:52 |
| Data point term sent to Coder | System | 19 Aug 2020 22:48:08 |
| User entered 'attention deficiency disorder' | (b) (4), (b) (6) | 19 Aug 2020 22:48:05 |

US3592229

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|---|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:30:20 |
| User closed query 'Data entered is non-conformant. Please correct.' (Site from System). | (b) (4) | 19 Aug 2020 22:49:00 |
| User entered 'un Mar 2014' reason for change: Data Entry Error | System | 19 Aug 2020 22:49:00 |
| User opened query 'Data entered is non-conformant. Please correct.' (Site from System). | (b) (4), (b) (6) | 19 Aug 2020 22:48:05 |
| User entered ' Mar 2014' (non-conformant). | System | 19 Aug 2020 22:48:05 |
| | (b) (4), (b) (6) | 19 Aug 2020 22:48:05 |

US3592229

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:21:23

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:30:20 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 19 Aug 2020 22:48:05 |

US3592229

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:21:23

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:30:20 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 19 Aug 2020 22:48:05 |

US3592229

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:30:20 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 19 Aug 2020 22:48:05 |

US3592229

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:21:23

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:30:20 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 19 Aug 2020 22:48:05 |

US3592229

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |
| User entered 'Mar 2014' | System | 19 Aug 2020 22:49:00 |
| User entered empty. | System | 19 Aug 2020 22:48:05 |

US3592229

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:21:23

Start Year (derived)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |
| User entered '2014' | System | 19 Aug 2020 22:49:00 |
| User entered empty. | System | 19 Aug 2020 22:48:05 |

US3592229

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |
| User entered empty. | System | 19 Aug 2020 22:48:05 |

US3592229

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |
| User entered empty. | System | 19 Aug 2020 22:48:05 |

US3592229

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:21:23

[Condition](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:30:20 |
| User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Upper respiratory tract disorders (excl infections), HLT: Laryngeal spasm, oedema and obstruction, PT: Laryngeal stenosis, LLT: Subglottic stenosis - version MedDRA\\23.0. | (b) (4) Coder Import (b) (4) | 17 Sep 2020 15:57:45 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 17 Sep 2020 15:57:45 |
| Data point term sent to Coder | System | 17 Sep 2020 15:56:28 |
| User entered 'subglottic stenosis' | (b) (4), (b) (6) | 17 Sep 2020 15:56:16 |

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Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:30:20 |
| User entered 'un Mar 2018' | (b) (4) (b) (4), (b) (6) | 17 Sep 2020 15:56:16 |

US3592229

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:21:23

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:30:20 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 17 Sep 2020 15:56:16 |

US3592229

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:21:23

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:30:20 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 17 Sep 2020 15:56:16 |

US3592229

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:30:20 |
| User entered 'un Mar 2018' | (b) (4) (b) (4), (b) (6) | 17 Sep 2020 15:56:16 |

US3592229

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:21:23

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:30:20 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 17 Sep 2020 15:56:16 |

US3592229

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |
| User entered 'Mar 2018' | System | 17 Sep 2020 15:56:16 |

US3592229

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:21:23

Start Year (derived)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |
| User entered '2018' | System | 17 Sep 2020 15:56:16 |

US3592229

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |
| User entered 'Mar 2018' | System | 17 Sep 2020 15:56:16 |

US3592229

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |
| User entered '2018' | System | 17 Sep 2020 15:56:16 |

US3592229

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:21:23

[Condition](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:30:20 |
| 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) (4), (b) (6) | 13 Oct 2020 07:15:22 |
| 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 'confirm this is already entered' (Site from DM). | (b) (4), (b) (6) | 08 Oct 2020 14:52:56 |
| 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) | 07 Oct 2020 10:23:12 |
| User coded data point as SOC: Surgical and medical procedures, HLGT: Gastrointestinal therapeutic procedures, HLT: Gastrointestinal therapeutic procedures NEC, PT: Gastrointestinal endoscopic therapy, LLT: Gastrointestinal endoscopic therapy - version MedDRA\23.0. | Coder Import (b) (4) (b) (4) | 25 Sep 2020 07:22:40 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0. | Coder Import (b) (4) (b) (4) | 25 Sep 2020 07:22:40 |
| Data point term sent to Coder | System | 17 Sep 2020 15:57:31 |
| User entered 'endoscopic dilation' | (b) (4), (b) (6) | 17 Sep 2020 15:57:03 |

US3592229

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:30:20 |
| User entered 'un Mar 2018' | (b) (4) (b) (4), (b) (6) | 17 Sep 2020 15:57:03 |

US3592229

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:21:23

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:30:20 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 17 Sep 2020 15:57:03 |

US3592229

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:21:23

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:30:20 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 17 Sep 2020 15:57:03 |

US3592229

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:30:20 |
| User entered 'un Mar 2018' | (b) (4) (b) (4), (b) (6) | 17 Sep 2020 15:57:03 |

US3592229

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:21:23

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:30:20 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 17 Sep 2020 15:57:03 |

US3592229

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |
| User entered 'Mar 2018' | System | 17 Sep 2020 15:57:03 |

US3592229

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:21:23

Start Year (derived)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |
| User entered '2018' | System | 17 Sep 2020 15:57:03 |

US3592229

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |
| User entered 'Mar 2018' | System | 17 Sep 2020 15:57:03 |

US3592229

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |
| User entered '2018' | System | 17 Sep 2020 15:57:03 |

US3592229

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:21:23

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:30:20 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 19 Aug 2020 22:50:40 |

US3592229

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:21:23

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:30:20 |
| User entered '18 Aug 2020' | (b) (4) (b) (4), (b) (6) | 19 Aug 2020 22:50:40 |

US3592229

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:30:20 |
| User entered '17:23' | (b) (4) (b) (4), (b) (6) | 19 Aug 2020 22:50:40 |

US3592229

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |
| User entered '18 Aug 2020 17:23' | System | 19 Aug 2020 22:50:40 |

US3592229

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:30:20 |
| User entered '169.0' cm | (b) (4) | 19 Aug 2020 22:50:40 |
| DataPoint set to visible. | (b) (4), (b) (6) | 18 Aug 2020 23:30:36 |
| | System | |

US3592229

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|---------------------------|----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:30:20 |
| User entered '100.8' kg | (b) (4) | 19 Aug 2020 22:50:40 |
| DataPoint set to visible. | (b) (4), (b) (6) System | 18 Aug 2020 23:30:36 |

US3592229

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:21:23

BMI (xxx.x)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |
| Amendment Manager: User entered '35.29288' | System | 17 Sep 2020 00:13:13 |
| User entered '35.3' | System | 19 Aug 2020 22:50:40 |
| DataPoint set to visible. | System | 18 Aug 2020 23:30:36 |

US3592229

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:21:23

[BMI units](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |
| User entered 'kg/m2' | System | 19 Aug 2020 22:50:40 |
| DataPoint set to visible. | System | 18 Aug 2020 23:30:36 |

US3592229

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:21:23

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:30:20 |
| User closed query 'Per CDM: As per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP and DIASTOLIC BP and keep the units and route blank as applicable. Please update accordingly.' (Site from DM). | (b) (4) (b) (4), (b) (6) | 26 Aug 2020 11:31:41 |
| Query 'Per CDM: As per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP and DIASTOLIC BP and keep the units and route blank as applicable. Please update accordingly.' answered with 'removed VS per CCGs' (Site from DM). | (b) (4), (b) (6) | 25 Aug 2020 19:43:05 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4), (b) (6) | 25 Aug 2020 19:42:35 |
| User opened query 'Per CDM: As per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP and DIASTOLIC BP and keep the units and route blank as applicable. Please update accordingly.' (Site from DM). | (b) (4), (b) (6) | 24 Aug 2020 06:53:22 |
| User entered '98.3' F | (b) (4), (b) (6) | 19 Aug 2020 22:50:40 |

US3592229

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:21:23

[Route of measurement](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:30:20 |
| User entered empty; reason for change Data Entry Error | (b) (4) (b) (4), (b) (6) | 25 Aug 2020 19:42:35 |
| User entered 'Oral (Oral)' | (b) (4), (b) (6) | 19 Aug 2020 22:50:40 |

US3592229

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:21:23

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:30:20 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 19 Aug 2020 22:50:40 |

US3592229

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:21:23

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:30:20 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4) (b) (4), (b) (6) | 25 Aug 2020 19:42:35 |
| User entered '77' | (b) (4), (b) (6) | 19 Aug 2020 22:50:40 |

US3592229

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:21:23

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |
| User entered 'bpm' | System | 19 Aug 2020 22:50:40 |

US3592229

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:30:20 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4) (b) (4), (b) (6) | 25 Aug 2020 19:42:35 |
| User entered '16' | (b) (4), (b) (6) | 19 Aug 2020 22:50:40 |

US3592229

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:21:23

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |
| User entered 'breaths/min' | System | 19 Aug 2020 22:50:40 |

US3592229

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:21:23

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:30:20 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4) | |
| | (b) (4), (b) (6) | 25 Aug 2020 19:42:35 |
| User closed query 'Systolic Blood Pressure reported is out of range < 85 or > 150 as required by protocol. Please confirm Systolic blood pressure is correct.' (Site from System). | (b) (4), (b) (6) | 20 Aug 2020 09:53:47 |
| Query 'Systolic Blood Pressure reported is out of range < 85 or > 150 as required by protocol. Please confirm Systolic blood pressure is correct.' answered with 'not clinically significant per investigator' (Site from System). | (b) (4), (b) (6) | 19 Aug 2020 22:50:59 |
| User opened query 'Systolic Blood Pressure reported is out of range < 85 or > 150 as required by protocol. Please confirm Systolic blood pressure is correct.' (Site from System). | System | 19 Aug 2020 22:50:40 |
| User entered '172' | (b) (4), (b) (6) | 19 Aug 2020 22:50:40 |

US3592229

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:21:23

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |
| User entered 'mmHg' | System | 19 Aug 2020 22:50:40 |

US3592229

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:30:20 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4) (b) (4), (b) (6) | 25 Aug 2020 19:42:35 |
| User entered '97' | (b) (4), (b) (6) | 19 Aug 2020 22:50:40 |

US3592229

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:21:23

Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |
| User entered 'mmHg' | System | 19 Aug 2020 22:50:40 |

US3592229

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:21:23

[Height \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |

US3592229

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:21:23

Weight (derived)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |

US3592229

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 08:21:23

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:30:20 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | (b) (4) (b) (4), (b) (6) | 17 Sep 2020 16:16:15 |
| User entered 'No (N)' reason for change: Data Entry Error | (b) (4), (b) (6) | 25 Aug 2020 19:54:18 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 19 Aug 2020 22:51:15 |

US3592229

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 08:21:23

Date of examination (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:30:20 |
| User entered '18 Aug 2020' reason for change: Data Entry Error | (b) (4) (b) (4), (b) (6) | 17 Sep 2020 16:16:15 |
| User entered empty; reason for change Data Entry Error | (b) (4), (b) (6) | 25 Aug 2020 19:54:18 |
| User entered '18 Aug 2020' | (b) (4), (b) (6) | 19 Aug 2020 22:51:15 |

US3592229

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:21:23

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:30:20 |
| User entered '18 Aug 2020' | (b) (4) (b) (4), (b) (6) | 19 Aug 2020 22:52:10 |

US3592229

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:21:23

[Is the participant of childbearing potential?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:30:20 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 19 Aug 2020 22:52:10 |

US3592229

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:21:23

[If No, what is the reason?](#)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:30:20 |
| User entered 'Post-menopausal (POST-MENOPAUSAL)' | (b) (4) (b) (4), (b) (6) | 19 Aug 2020 22:52:10 |

US3592229

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:21:23

If Partner medically sterile or Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:30:20 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 19 Aug 2020 22:52:10 |

US3592229

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:30:20 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 19 Aug 2020 22:52:10 |

US3592229

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:21:23

Date of surgery unknown

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:30:20 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 19 Aug 2020 22:52:10 |

US3592229

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:30:20 |
| User entered 'un Jan 2018' reason for change: Data Entry Error | (b) (4) (b) (4), (b) (6) | 01 Oct 2020 21:02:37 |
| User entered empty. | (b) (4), (b) (6) | 19 Aug 2020 22:52:10 |

US3592229

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:21:23

[Date of last menstruation unknown](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:30:20 |
| User entered '0' reason for change: Data Entry Error | (b) (4) (b) (4), (b) (6) | 01 Oct 2020 21:02:37 |
| User entered '1' | (b) (4), (b) (6) | 19 Aug 2020 22:52:10 |

US3592229

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:21:23

[Healthcare workers](#) (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:30:20 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 19 Aug 2020 22:52:58 |

US3592229

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:21:23

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:30:20 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 19 Aug 2020 22:52:58 |

US3592229

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:21:23

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:30:20 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 19 Aug 2020 22:52:58 |

US3592229

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:21:23

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:30:20 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 19 Aug 2020 22:52:58 |

US3592229

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:21:23

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:30:20 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 19 Aug 2020 22:52:58 |

US3592229

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:21:23

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:30:20 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 19 Aug 2020 22:52:58 |

US3592229

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:21:23

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:30:20 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 19 Aug 2020 22:52:58 |

US3592229

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:21:23

[Personal Care and in-home services](#) (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:30:20 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 19 Aug 2020 22:52:58 |

US3592229

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:21:23

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:30:20 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 19 Aug 2020 22:52:58 |

US3592229

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:21:23

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:30:20 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 19 Aug 2020 22:52:58 |

US3592229

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:21:23

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:30:20 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 19 Aug 2020 22:52:58 |

US3592229

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:21:23

[Other](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:30:20 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 19 Aug 2020 22:52:58 |

US3592229

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:21:23

[Specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:30:20 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 19 Aug 2020 22:52:58 |

US3592229

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:21:23

No Risk Identified

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:30:20 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 19 Aug 2020 22:52:58 |

US3592229

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:30:20 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 19 Aug 2020 22:52:58 |

US3592229

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:21:23

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:30:20 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 19 Aug 2020 22:52:58 |

US3592229

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:21:23

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:30:20 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 19 Aug 2020 22:52:58 |

US3592229

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:21:23

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:30:20 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 19 Aug 2020 22:52:58 |

US3592229

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:30:20 |
| User entered 'l' | (b) (4) (b) (4), (b) (6) | 19 Aug 2020 22:52:58 |

US3592229

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:21:23

[Other](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:30:20 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 19 Aug 2020 22:52:58 |

US3592229

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:21:23

[Specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:13:23 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:30:20 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 19 Aug 2020 22:52:58 |

US3592229

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:21:23

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:00:40 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 19 Aug 2020 22:27:27 |

US3592229

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:00:40 |
| User entered '18 Aug 2020' | (b) (4) (b) (4), (b) (6) | 19 Aug 2020 22:27:27 |

US3592229

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:21:23

[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 10:26:11 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:00:40 |
| User entered 'Clinic (Clinic)' | (b) (4) (b) (4), (b) (6) | 19 Aug 2020 22:27:27 |

US3592229

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:21:23

[Folder OID](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User entered 'VISIT1' | System | 19 Aug 2020 22:27:27 |

US3592229

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:00:40 |
| User entered '18 AUG 2020' | (b) (4) RWS_ENDPOINT ENDPOINT (b) (4) | 18 Aug 2020 23:14:09 |

US3592229

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:00:40 |
| Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System). | (b) (4) | 21 Aug 2020 05:27:36 |
| Amendment Manager: Data point set to conformant. | System | 21 Aug 2020 05:27:35 |
| User opened query 'Data entered is non-conformant. Please correct.' (Site from System). | System | 18 Aug 2020 23:14:09 |
| User entered '105768' (non-conformant). | RWS_ENDPOINT ENDPOINT (b) (4) | 18 Aug 2020 23:14:09 |

US3592229

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|---|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:00:40 |
| User entered '>=18 and <65 years and not at risk (1)' | (b) (4) RWS_ENDPOINT ENDPOINT (b) (4) | 18 Aug 2020 23:14:09 |

US3592229

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:21:23

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 10:26:11 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:00:40 |
| User closed query 'Per CDM: Please complete this section of the form.' (Site from DM). | (b) (4) (b) (4), (b) (6) | 10 Sep 2020 13:29:17 |
| Query 'Per CDM: Please complete this section of the form.' answered with 'data updated' (Site from DM). | (b) (4), (b) (6) | 08 Sep 2020 23:02:09 |
| User entered 'No (N)' | (b) (4), (b) (6) | 08 Sep 2020 23:01:38 |
| User opened query 'Per CDM: Please complete this section of the form.' (Site from DM). | (b) (4), (b) (6) | 01 Sep 2020 13:32:06 |

US3592229

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:21:23

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 10:26:11 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:00:40 |
| User closed query 'Data is required. Please complete.' (Site from System). | (b) (4) | 08 Sep 2020 23:02:15 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 08 Sep 2020 23:02:15 |
| User entered 'No (N)' reason for change: Data Entry Error | (b) (4), (b) (6) | 08 Sep 2020 23:02:15 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 08 Sep 2020 23:01:38 |
| User entered empty. | (b) (4), (b) (6) | 08 Sep 2020 23:01:38 |

US3592229

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:00:40 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 08 Sep 2020 23:01:38 |

US3592229

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:21:23

Diabetes (Type I, Type 2, or gestational)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:00:40 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 08 Sep 2020 23:01:38 |

US3592229

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:21:23

[Liver Disease](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:00:40 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 08 Sep 2020 23:01:38 |

US3592229

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:00:40 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 23 Sep 2020 17:09:03 |
| Amendment Manager: DataPoint set to visible. | System | 19 Sep 2020 10:35:23 |
| Amendment Manager inserted this DataPoint. | System | 19 Sep 2020 01:25:52 |

US3592229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:21:23

[Height](#)

| Audit | User | Time (GMT) |
|---|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:00:40 |
| User entered missing code ND - Not Done; reason for | (b) (4) | |
| change Data Entry Error | (b) (4), (b) (6) | 26 Aug 2020 21:53:10 |
| User entered '169.0' cm | (b) (4), (b) (6) | 19 Aug 2020 22:33:15 |

US3592229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:21:23

Weight

| Audit | User | Time (GMT) |
|---|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:00:40 |
| User entered missing code ND - Not Done; reason for | (b) (4) | |
| change Data Entry Error | (b) (4), (b) (6) | 26 Aug 2020 21:53:10 |
| User entered '100.8' kg | (b) (4), (b) (6) | 19 Aug 2020 22:33:15 |

US3592229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:21:23

[Height](#)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:00:40 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4) (b) (4), (b) (6) | 26 Aug 2020 21:53:10 |
| User entered '169.0' cm | (b) (4), (b) (6) | 19 Aug 2020 22:33:15 |

US3592229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:21:23

[Weight](#)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:00:40 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4) (b) (4), (b) (6) | 26 Aug 2020 21:53:10 |
| User entered '100.8' kg | (b) (4), (b) (6) | 19 Aug 2020 22:33:15 |

US3592229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:21:23

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User accepted default value 'Pre-Dose (PREDOSE)' | (b) (4), (b) (6) | 19 Aug 2020 22:33:15 |

US3592229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:21:23

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:00:40 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 19 Aug 2020 22:33:15 |

US3592229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:21:23

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:00:40 |
| User entered '18 Aug 2020' | (b) (4) (b) (4), (b) (6) | 19 Aug 2020 22:33:15 |

US3592229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:00:40 |
| User entered '17:23' | (b) (4) (b) (4), (b) (6) | 19 Aug 2020 22:33:15 |

US3592229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User entered '18 Aug 2020 17:23' | System | 19 Aug 2020 22:33:15 |

US3592229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:21:23

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:00:40 |
| User entered '98.3' F | (b) (4) (b) (4), (b) (6) | 19 Aug 2020 22:33:15 |

US3592229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:21:23

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:00:40 |
| User entered 'Oral (Oral)' | (b) (4) (b) (4), (b) (6) | 19 Aug 2020 22:33:15 |

US3592229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:21:23

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:00:40 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 19 Aug 2020 22:33:15 |

US3592229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:21:23

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:00:40 |
| User entered '77' | (b) (4) (b) (4), (b) (6) | 19 Aug 2020 22:33:15 |

US3592229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:21:23

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User entered 'bpm' | System | 19 Aug 2020 22:33:15 |

US3592229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:00:40 |
| User entered '16' | (b) (4) (b) (4), (b) (6) | 19 Aug 2020 22:33:15 |

US3592229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:21:23

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User entered 'breaths/min' | System | 19 Aug 2020 22:33:15 |

US3592229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:21:23

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:00:40 |
| User closed query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System). | (b) (4) (b) (4), (b) (6) | 20 Aug 2020 09:54:02 |
| Query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'not clinically significant per investigator' (Site from System). | (b) (4), (b) (6) | 19 Aug 2020 22:33:47 |
| User opened query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System). | System | 19 Aug 2020 22:33:15 |
| User entered '172' | (b) (4), (b) (6) | 19 Aug 2020 22:33:15 |

US3592229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:21:23

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User entered 'mmHg' | System | 19 Aug 2020 22:33:15 |

US3592229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:21:23

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:00:40 |
| User entered '97' | (b) (4) (b) (4), (b) (6) | 19 Aug 2020 22:33:15 |

US3592229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:21:23

Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User entered 'mmHg' | System | 19 Aug 2020 22:33:15 |

US3592229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:21:23

[Height](#)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:00:40 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4) (b) (4), (b) (6) | 26 Aug 2020 21:53:10 |
| User entered '169.0' cm | (b) (4), (b) (6) | 19 Aug 2020 22:33:15 |

US3592229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:21:23

[Weight](#)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:00:40 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4) (b) (4), (b) (6) | 26 Aug 2020 21:53:10 |
| User entered '100.8' kg | (b) (4), (b) (6) | 19 Aug 2020 22:33:15 |

US3592229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:21:23

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User accepted default value 'Post-Dose (POSTDOSE)' | (b) (4), (b) (6) | 19 Aug 2020 22:33:15 |

US3592229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:21:23

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:00:40 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 19 Aug 2020 22:33:15 |

US3592229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:21:23

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:00:40 |
| User entered '18 Aug 2020' | (b) (4) (b) (4), (b) (6) | 19 Aug 2020 22:33:15 |

US3592229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:00:40 |
| 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) | 20 Aug 2020 09:54:45 |
| Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with 'entry is correct' (Site from System). | (b) (4), (b) (6) | 19 Aug 2020 22:34:15 |
| User opened query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System). | | 19 Aug 2020 22:33:15 |
| User entered '18:57' | (b) (4), (b) (6) | 19 Aug 2020 22:33:15 |

US3592229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User entered '18 Aug 2020 18:57' | System | 19 Aug 2020 22:33:15 |

US3592229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:21:23

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:00:40 |
| User entered '97.9' F | (b) (4) (b) (4), (b) (6) | 19 Aug 2020 22:33:15 |

US3592229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:21:23

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:00:40 |
| User entered 'Oral (Oral)' | (b) (4) (b) (4), (b) (6) | 19 Aug 2020 22:33:15 |

US3592229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:21:23

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:00:40 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 19 Aug 2020 22:33:15 |

US3592229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:21:23

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:00:40 |
| User entered '80' | (b) (4) (b) (4), (b) (6) | 19 Aug 2020 22:33:15 |

US3592229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:21:23

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User entered 'bpm' | System | 19 Aug 2020 22:33:15 |

US3592229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:00:40 |
| User entered '16' | (b) (4) (b) (4), (b) (6) | 19 Aug 2020 22:33:15 |

US3592229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:21:23

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User entered 'breaths/min' | System | 19 Aug 2020 22:33:15 |

US3592229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:21:23

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:00:40 |
| User closed query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System). | (b) (4) (b) (4), (b) (6) | 20 Aug 2020 09:54:17 |
| Query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'not clinically significant per investigator' (Site from System). | (b) (4), (b) (6) | 19 Aug 2020 22:34:39 |
| User opened query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System). | System | 19 Aug 2020 22:33:15 |
| User entered '159' | (b) (4), (b) (6) | 19 Aug 2020 22:33:15 |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:21:23

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User entered 'mmHg' | System | 19 Aug 2020 22:33:15 |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:21:23

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:00:40 |
| User entered '75' | (b) (4) (b) (4), (b) (6) | 19 Aug 2020 22:33:15 |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:21:23

Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User entered 'mmHg' | System | 19 Aug 2020 22:33:15 |

US3592229

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 08:21:23

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:00:40 |
| User entered 'No (N)' reason for change: Data Entry Error | (b) (4) (b) (4), (b) (6) | 17 Sep 2020 16:16:27 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 19 Aug 2020 22:34:59 |

US3592229

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 08:21:23

Date of examination (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:00:40 |
| User entered empty; reason for change Data Entry Error | (b) (4) (b) (4), (b) (6) | 17 Sep 2020 16:16:27 |
| User entered '18 Aug 2020' | (b) (4), (b) (6) | 19 Aug 2020 22:34:59 |

US3592229

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:21:23

[Was study treatment given?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:00:40 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 18 Aug 2020 23:31:01 |

US3592229

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:21:23

[If No, reason not given](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:00:40 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 18 Aug 2020 23:31:01 |

US3592229

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:21:23

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 10:26:11 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:00:40 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 18 Aug 2020 23:31:01 |

US3592229

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:21:23

[What was the study treatment?](#)

| Audit | User | Time (GMT) |
|-------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User entered 'MRNA-1273 OR PLACEBO' | System | 18 Aug 2020 23:31:01 |

US3592229

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:21:23

What was the treatment date? (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:00:40 |
| User entered '18 Aug 2020' | (b) (4) (b) (4), (b) (6) | 18 Aug 2020 23:31:01 |

US3592229

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:00:40 |
| User entered '18:26' | (b) (4) (b) (4), (b) (6) | 18 Aug 2020 23:31:01 |

US3592229

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User entered '18 Aug 2020 18:26' | System | 18 Aug 2020 23:31:01 |

US3592229

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|------------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:00:40 |
| User entered 'Left Arm (LEFT ARM)' | (b) (4) (b) (4), (b) (6) | 18 Aug 2020 23:31:01 |

US3592229

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:21:23

What was the frequency of the study treatment dosing?

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User entered 'ONCE' | System | 18 Aug 2020 23:31:01 |

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:21:23

What was the route of administration for the study treatment?

| Audit | User | Time (GMT) |
|------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User entered 'INTRAMUSCULAR' | System | 18 Aug 2020 23:31:01 |

US3592229

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:21:23

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:00:40 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 19 Aug 2020 22:35:53 |

US3592229

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:21:23

Collection date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:00:40 |
| User entered '18 Aug 2020' | (b) (4) (b) (4), (b) (6) | 19 Aug 2020 22:35:53 |

US3592229

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:21:23

Collection time (00:00-23:59)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User signature succeeded. | Terry Poling (b) (4) (b) (4) | 05 Mar 2021 16:00:40 |
| User closed query 'Data is required. Please provide.' (Site from System). | System | 15 Sep 2020 16:26:51 |
| User entered '18:07' reason for change: Data Entry Error | (b) (4), (b) (6) | 15 Sep 2020 16:26:51 |
| User opened query 'Data is required. Please provide.' (Site from System). | System | 19 Aug 2020 22:35:53 |
| User entered empty. | (b) (4), (b) (6) | 19 Aug 2020 22:35:53 |

US3592229

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User entered '18 Aug 2020 18:07' | System | 15 Sep 2020 16:26:51 |
| User entered empty. | System | 19 Aug 2020 22:35:53 |

US3592229

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 08:21:23

Collection date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:00:40 |
| User entered '18 Aug 2020' | (b) (4) (b) (4), (b) (6) | 19 Aug 2020 22:37:05 |

US3592229

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:21:23

[Lab Test](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)' | (b) (4), (b) (6) | 19 Aug 2020 22:37:05 |

US3592229

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:21:23

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:00:40 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 19 Aug 2020 22:37:05 |

US3592229

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:21:23

Collection time (00:00 - 23:59)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:00:40 |
| User entered '18:00' | (b) (4) (b) (4), (b) (6) | 19 Aug 2020 22:37:05 |

US3592229

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User entered '18 Aug 2020 18:00' | System | 19 Aug 2020 22:37:05 |

US3592229

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:21:23

[Lab Test](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)' | (b) (4), (b) (6) | 19 Aug 2020 22:37:05 |

US3592229

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:21:23

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:00:40 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 19 Aug 2020 22:37:05 |

US3592229

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:21:23

Collection time (00:00 - 23:59)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:00:40 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 19 Aug 2020 22:37:05 |

US3592229

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User entered empty. | System | 19 Aug 2020 22:37:05 |

US3592229

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 08:21:23

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:00:40 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 19 Aug 2020 22:37:19 |

US3592229

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 08:21:23

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User entered 'l' | System | 19 Aug 2020 22:37:19 |

US3592229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:21:23

TIMEPOINT

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| Data entry locked. | System | 18 Aug 2020 23:31:01 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 18 Aug 2020 23:31:01 |

US3592229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:21:23

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-08-18T18:59:53', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: 'dfcb7291-8679-4be0-a181-279a96ce8dc2' | System | 19 Aug 2020 00:00:51 |
| User entered 'Yes (Y)' | System | 19 Aug 2020 00:00:51 |

US3592229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:21:23

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-08-18T19:00:36', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: 'dfcb7291-8679-4be0-a181-279a96ce8dc2' User entered '97.9' | System | 19 Aug 2020 00:00:51 |
| | System | 19 Aug 2020 00:00:51 |

US3592229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-08-18T19:00:43', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: 'dfcb7291-8679-4be0-a181-279a96ce8dc2' | System | 19 Aug 2020 00:00:51 |
| User entered 'No (N)' | System | 19 Aug 2020 00:00:51 |

US3592229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:21:23

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-08-18T19:00:49', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: 'dfcb7291-8679-4be0-a181-279a96ce8dc2' | System | 19 Aug 2020 00:00:51 |
| User entered '18 Aug 2020 19:00' | System | 19 Aug 2020 00:00:51 |

US3592229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:21:23

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| User entered '18 Aug 2020 18:46' | System | 18 Aug 2020 23:31:01 |

US3592229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:21:23

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| User entered '18 Aug 2020 21:16' | System | 18 Aug 2020 23:31:01 |

US3592229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:21:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| Data entry locked. | System | 18 Aug 2020 23:31:01 |
| User entered 'Day 1, after vaccination (at home)' | System | 18 Aug 2020 23:31:01 |

US3592229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:21:23

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-08-19T06:16:41', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '7059f319-5c12-42f9-b773-5b1b2ff78568' | System | 19 Aug 2020 11:17:15 |
| User entered 'Yes (Y)' | System | 19 Aug 2020 11:17:15 |

US3592229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:21:23

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-08-19T06:16:54', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '7059f319-5c12-42f9-b773-5b1b2ff78568' User entered '96.8' | System | 19 Aug 2020 11:17:15 |
| | System | 19 Aug 2020 11:17:15 |

US3592229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-08-19T06:16:58', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '7059f319-5c12-42f9-b773-5b1b2ff78568' | System | 19 Aug 2020 11:17:15 |
| User entered 'No (N)' | System | 19 Aug 2020 11:17:15 |

US3592229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:21:23

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-08-19T06:17:11', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '7059f319-5c12-42f9-b773-5b1b2ff78568' | System | 19 Aug 2020 11:17:15 |
| User entered '19 Aug 2020 06:17' | System | 19 Aug 2020 11:17:15 |

US3592229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:21:23

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| User entered '18 Aug 2020 22:11' | System | 18 Aug 2020 23:31:01 |

US3592229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:21:23

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| User entered '19 Aug 2020 11:59' | System | 18 Aug 2020 23:31:01 |

US3592229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:21:23

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| Data entry locked. | System | 18 Aug 2020 23:31:01 |
| User entered 'Day 2' | System | 18 Aug 2020 23:31:01 |

US3592229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:21:23

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-08-19T15:49:35', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '2d5de238-5e67-493b-beaf-6794dd2a9db6' | System | 19 Aug 2020 20:51:27 |
| User entered 'Yes (Y)' | System | 19 Aug 2020 20:51:27 |

US3592229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:21:23

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-08-19T15:51:14', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '2d5de238-5e67-493b-beaf-6794dd2a9db6' User entered '97.9' | System | 19 Aug 2020 20:51:27 |
| | System | 19 Aug 2020 20:51:27 |

US3592229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-08-19T15:51:18', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '2d5de238-5e67-493b-beaf-6794dd2a9db6' | System | 19 Aug 2020 20:51:27 |
| User entered 'No (N)' | System | 19 Aug 2020 20:51:27 |

US3592229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:21:23

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-08-19T15:51:24', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '2d5de238-5e67-493b-beaf-6794dd2a9db6' | System | 19 Aug 2020 20:51:27 |
| User entered '19 Aug 2020 15:51' | System | 19 Aug 2020 20:51:27 |

US3592229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:21:23

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| User entered '19 Aug 2020 12:00' | System | 18 Aug 2020 23:31:01 |

US3592229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:21:23

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| User entered '20 Aug 2020 11:59' | System | 18 Aug 2020 23:31:01 |

US3592229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:21:23

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| Data entry locked. | System | 18 Aug 2020 23:31:01 |
| User entered 'Day 3' | System | 18 Aug 2020 23:31:01 |

US3592229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:21:23

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-08-21T07:18:22', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: 'abaadff4-35e2-4227-bc5f-d4ed69254391' | System | 21 Aug 2020 12:18:40 |
| User entered 'Yes (Y)' | System | 21 Aug 2020 12:18:40 |

US3592229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:21:23

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-08-21T07:18:31', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: 'abaadff4-35e2-4227-bc5f-d4ed69254391' | System | 21 Aug 2020 12:18:40 |
| User entered '97.6' | System | 21 Aug 2020 12:18:40 |

US3592229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-08-21T07:18:35', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: 'abaadff4-35e2-4227-bc5f-d4ed69254391' | System | 21 Aug 2020 12:18:40 |
| User entered 'No (N)' | System | 21 Aug 2020 12:18:40 |

US3592229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:21:23

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-08-21T07:18:39', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: 'abaadff4-35e2-4227-bc5f-d4ed69254391' | System | 21 Aug 2020 12:18:40 |
| User entered '21 Aug 2020 07:18' | System | 21 Aug 2020 12:18:40 |

US3592229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:21:23

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| User entered '20 Aug 2020 12:00' | System | 18 Aug 2020 23:31:01 |

US3592229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:21:23

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| User entered '21 Aug 2020 11:59' | System | 18 Aug 2020 23:31:01 |

US3592229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:21:23

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| Data entry locked. | System | 18 Aug 2020 23:31:01 |
| User entered 'Day 4' | System | 18 Aug 2020 23:31:01 |

US3592229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:21:23

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-08-22T07:39:16', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: 'b7e924cb-3488-4d4d-8c48-ca609df85c3f' User entered 'Yes (Y)' | System | 22 Aug 2020 12:39:45 |
| | System | 22 Aug 2020 12:39:45 |

US3592229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:21:23

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-08-22T07:39:32', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: 'b7e924cb-3488-4d4d-8c48-ca609df85c3f' User entered '97.5' | System | 22 Aug 2020 12:39:45 |
| | System | 22 Aug 2020 12:39:45 |

US3592229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-08-22T07:39:37', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: 'b7e924cb-3488-4d4d-8c48-ca609df85c3f' User entered 'No (N)' | System | 22 Aug 2020 12:39:45 |
| | System | 22 Aug 2020 12:39:45 |

US3592229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:21:23

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-08-22T07:39:43', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: 'b7e924cb-3488-4d4d-8c48-ca609df85c3f' User entered '22 Aug 2020 07:39' | System | 22 Aug 2020 12:39:45 |
| | System | 22 Aug 2020 12:39:45 |

US3592229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:21:23

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| User entered '21 Aug 2020 12:00' | System | 18 Aug 2020 23:31:01 |

US3592229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:21:23

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| User entered '22 Aug 2020 11:59' | System | 18 Aug 2020 23:31:01 |

US3592229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:21:23

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| Data entry locked. | System | 18 Aug 2020 23:31:01 |
| User entered 'Day 5' | System | 18 Aug 2020 23:31:01 |

US3592229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:21:23

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-08-23T08:50:26', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '52644d53-9a4a-45af-8ee4-d116f568391b' User entered 'Yes (Y)' | System | 23 Aug 2020 13:50:45 |
| | System | 23 Aug 2020 13:50:45 |

US3592229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:21:23

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-08-23T08:50:31', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '52644d53-9a4a-45af-8ee4-d116f568391b' User entered '97.6' | System | 23 Aug 2020 13:50:45 |
| | System | 23 Aug 2020 13:50:45 |

US3592229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-08-23T08:50:38', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '52644d53-9a4a-45af-8ee4-d116f568391b' User entered 'No (N)' | System | 23 Aug 2020 13:50:45 |
| | System | 23 Aug 2020 13:50:45 |

US3592229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:21:23

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-08-23T08:50:41', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '52644d53-9a4a-45af-8ee4-d116f568391b' User entered '23 Aug 2020 08:50' | System | 23 Aug 2020 13:50:45 |
| | System | 23 Aug 2020 13:50:45 |

US3592229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:21:23

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| User entered '22 Aug 2020 12:00' | System | 18 Aug 2020 23:31:01 |

US3592229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:21:23

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| User entered '23 Aug 2020 11:59' | System | 18 Aug 2020 23:31:01 |

US3592229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:21:23

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| Data entry locked. | System | 18 Aug 2020 23:31:01 |
| User entered 'Day 6' | System | 18 Aug 2020 23:31:01 |

US3592229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:21:23

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-08-23T14:20:10', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: 'd2683362-ebca-459c-b79a-7c04a49bfcfa' | System | 23 Aug 2020 19:20:47 |
| User entered 'Yes (Y)' | System | 23 Aug 2020 19:20:47 |

US3592229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:21:23

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-08-23T14:20:26', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: 'd2683362-ebca-459c-b79a-7c04a49bfcfa' User entered '100.6' | System | 23 Aug 2020 19:20:47 |
| | System | 23 Aug 2020 19:20:47 |

US3592229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-08-23T14:20:31', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: 'd2683362-ebca-459c-b79a-7c04a49bfcfa' | System | 23 Aug 2020 19:20:47 |
| User entered 'Yes (Y)' | System | 23 Aug 2020 19:20:47 |

US3592229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| 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 'Subject took Ibuprofen for urinary tract infection.' (Site from System). | (b) (4), (b) (6) | 22 Sep 2020 04:06:01 |
| 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). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-08-23T14:20:42', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: 'd2683362-ebca-459c-b79a-7c04a49bfcfa' User entered '1' | (b) (4), (b) (6) | 17 Sep 2020 16:00:38 |
| 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 | 23 Aug 2020 19:20:47 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-08-23T14:20:42', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: 'd2683362-ebca-459c-b79a-7c04a49bfcfa' User entered '1' | System | 23 Aug 2020 19:20:47 |
| User entered '1' | System | 23 Aug 2020 19:20:47 |

US3592229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:21:23

To **PREVENT** pain or fever from occurring

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-08-23T14:20:42', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: 'd2683362-ebca-459c-b79a-7c04a49bfcfa' User entered '0' | System | 23 Aug 2020 19:20:47 |
| | System | 23 Aug 2020 19:20:47 |

US3592229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:21:23

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-08-23T14:20:46', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: 'd2683362-ebca-459c-b79a-7c04a49bfcfa' | System | 23 Aug 2020 19:20:47 |
| User entered '23 Aug 2020 14:20' | System | 23 Aug 2020 19:20:47 |

US3592229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:21:23

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| User entered '23 Aug 2020 12:00' | System | 18 Aug 2020 23:31:01 |

US3592229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:21:23

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| User entered '24 Aug 2020 11:59' | System | 18 Aug 2020 23:31:01 |

US3592229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:21:23

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| Data entry locked. | System | 18 Aug 2020 23:31:01 |
| User entered 'Day 7' | System | 18 Aug 2020 23:31:01 |

US3592229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:21:23

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-08-24T15:50:07', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '6ac21850-8b5b-4073-af16-2f45bb7b5a15' | System | 24 Aug 2020 20:50:55 |
| User entered 'Yes (Y)' | System | 24 Aug 2020 20:50:55 |

US3592229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:21:23

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-08-24T15:50:14', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '6ac21850-8b5b-4073-af16-2f45bb7b5a15' User entered '97.8' | System | 24 Aug 2020 20:50:55 |
| | System | 24 Aug 2020 20:50:55 |

US3592229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-08-24T15:50:19', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '6ac21850-8b5b-4073-af16-2f45bb7b5a15' | System | 24 Aug 2020 20:50:55 |
| User entered 'No (N)' | System | 24 Aug 2020 20:50:55 |

US3592229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:21:23

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-08-24T15:50:22', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '6ac21850-8b5b-4073-af16-2f45bb7b5a15' User entered '24 Aug 2020 15:50' | System | 24 Aug 2020 20:50:55 |
| | System | 24 Aug 2020 20:50:55 |

US3592229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:21:23

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| User entered '24 Aug 2020 12:00' | System | 18 Aug 2020 23:31:01 |

US3592229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:21:23

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| User entered '25 Aug 2020 11:59' | System | 18 Aug 2020 23:31:01 |

US3592229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:21:23

TIMEPOINT

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| Data entry locked. | System | 18 Aug 2020 23:31:01 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 18 Aug 2020 23:31:01 |

US3592229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:21:23

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-08-18T19:00:58', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: 'd02c32be-7ed7-41b5-b810-4f61919b4bc5' | System | 19 Aug 2020 00:01:24 |
| User entered 'None (1)' | System | 19 Aug 2020 00:01:24 |

US3592229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:21:23

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-08-18T19:01:05', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: 'd02c32be-7ed7-41b5-b810-4f61919b4bc5' User entered 'No (N)' | System | 19 Aug 2020 00:01:24 |
| | System | 19 Aug 2020 00:01:24 |

US3592229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-08-18T19:01:09', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: 'd02c32be-7ed7-41b5-b810-4f61919b4bc5' User entered 'No (N)' | System | 19 Aug 2020 00:01:24 |
| | System | 19 Aug 2020 00:01:24 |

US3592229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:21:23

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-08-18T19:01:18', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: 'd02c32be-7ed7-41b5-b810-4f61919b4bc5' User entered 'None (1)' | System | 19 Aug 2020 00:01:24 |
| | System | 19 Aug 2020 00:01:24 |

US3592229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:21:23

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-08-18T19:01:22', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: 'd02c32be-7ed7-41b5-b810-4f61919b4bc5' User entered '18 Aug 2020 19:01' | System | 19 Aug 2020 00:01:24 |
| | System | 19 Aug 2020 00:01:24 |

US3592229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:21:23

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| User entered '18 Aug 2020 18:46' | System | 18 Aug 2020 23:31:01 |

US3592229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:21:23

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| User entered '18 Aug 2020 21:16' | System | 18 Aug 2020 23:31:01 |

US3592229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:21:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| Data entry locked. | System | 18 Aug 2020 23:31:01 |
| User entered 'Day 1, after vaccination (at home)' | System | 18 Aug 2020 23:31:01 |

US3592229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:21:23

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-08-19T06:17:25', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '14deb360-846c-4a85-b297-30c22d3b0bdf' | System | 19 Aug 2020 11:17:46 |
| User entered 'None (1)' | System | 19 Aug 2020 11:17:46 |

US3592229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:21:23

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-08-19T06:17:28', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '14deb360-846c-4a85-b297-30c22d3b0bdf' User entered 'No (N)' | System | 19 Aug 2020 11:17:46 |
| | System | 19 Aug 2020 11:17:46 |

US3592229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-08-19T06:17:31', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '14deb360-846c-4a85-b297-30c22d3b0bdf' User entered 'No (N)' | System | 19 Aug 2020 11:17:46 |
| | System | 19 Aug 2020 11:17:46 |

US3592229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:21:23

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-08-19T06:17:40', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '14deb360-846c-4a85-b297-30c22d3b0bdf' User entered 'None (1)' | System | 19 Aug 2020 11:17:46 |
| | System | 19 Aug 2020 11:17:46 |

US3592229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:21:23

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-08-19T06:17:45', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '14deb360-846c-4a85-b297-30c22d3b0bdf' User entered '19 Aug 2020 06:17' | System | 19 Aug 2020 11:17:46 |
| | System | 19 Aug 2020 11:17:46 |

US3592229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:21:23

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| User entered '18 Aug 2020 22:11' | System | 18 Aug 2020 23:31:01 |

US3592229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:21:23

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| User entered '19 Aug 2020 11:59' | System | 18 Aug 2020 23:31:01 |

US3592229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:21:23

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| Data entry locked. | System | 18 Aug 2020 23:31:01 |
| User entered 'Day 2' | System | 18 Aug 2020 23:31:01 |

US3592229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:21:23

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-08-19T15:51:33', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '05341932-f72f-4398-b474-97e04d1fcfc4' | System | 19 Aug 2020 20:51:58 |
| User entered 'None (1)' | System | 19 Aug 2020 20:51:58 |

US3592229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:21:23

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-08-19T15:51:36', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '05341932-f72f-4398-b474-97e04d1fcfc4' | System | 19 Aug 2020 20:51:58 |
| User entered 'No (N)' | System | 19 Aug 2020 20:51:58 |

US3592229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-08-19T15:51:43', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '05341932-f72f-4398-b474-97e04d1fcfc4' | System | 19 Aug 2020 20:51:58 |
| User entered 'No (N)' | System | 19 Aug 2020 20:51:58 |

US3592229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:21:23

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-08-19T15:51:52', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '05341932-f72f-4398-b474-97e04d1fcfc4' | System | 19 Aug 2020 20:51:58 |
| User entered 'None (1)' | System | 19 Aug 2020 20:51:58 |

US3592229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:21:23

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-08-19T15:51:56', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '05341932-f72f-4398-b474-97e04d1fcfc4' | System | 19 Aug 2020 20:51:58 |
| User entered '19 Aug 2020 15:51' | System | 19 Aug 2020 20:51:58 |

US3592229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:21:23

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| User entered '19 Aug 2020 12:00' | System | 18 Aug 2020 23:31:01 |

US3592229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:21:23

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| User entered '20 Aug 2020 11:59' | System | 18 Aug 2020 23:31:01 |

US3592229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:21:23

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| Data entry locked. | System | 18 Aug 2020 23:31:01 |
| User entered 'Day 3' | System | 18 Aug 2020 23:31:01 |

US3592229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:21:23

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-08-21T07:18:43', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '510e6ab8-e0b6-42d2-abbc-c0bb5fbd6776' | System | 21 Aug 2020 12:18:57 |
| User entered 'None (1)' | System | 21 Aug 2020 12:18:57 |

US3592229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:21:23

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-08-21T07:18:46', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '510e6ab8-e0b6-42d2-abbc-c0bb5fbd6776' User entered 'No (N)' | System | 21 Aug 2020 12:18:57 |
| | System | 21 Aug 2020 12:18:57 |

US3592229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-08-21T07:18:49', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '510e6ab8-e0b6-42d2-abbc-c0bb5fbd6776' User entered 'No (N)' | System | 21 Aug 2020 12:18:57 |
| | System | 21 Aug 2020 12:18:57 |

US3592229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:21:23

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-08-21T07:18:52', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '510e6ab8-e0b6-42d2-abbc-c0bb5fbd6776' User entered 'None (1)' | System | 21 Aug 2020 12:18:57 |
| | System | 21 Aug 2020 12:18:57 |

US3592229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:21:23

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-08-21T07:18:55', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '510e6ab8-e0b6-42d2-abbc-c0bb5fbd6776' User entered '21 Aug 2020 07:18' | System | 21 Aug 2020 12:18:57 |
| | System | 21 Aug 2020 12:18:57 |

US3592229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:21:23

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| User entered '20 Aug 2020 12:00' | System | 18 Aug 2020 23:31:01 |

US3592229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:21:23

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| User entered '21 Aug 2020 11:59' | System | 18 Aug 2020 23:31:01 |

US3592229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:21:23

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| Data entry locked. | System | 18 Aug 2020 23:31:01 |
| User entered 'Day 4' | System | 18 Aug 2020 23:31:01 |

US3592229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:21:23

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-08-22T07:39:47', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '6206a17d-f14a-40f1-bbe9-8d0591de7194' | System | 22 Aug 2020 12:40:01 |
| User entered 'None (1)' | System | 22 Aug 2020 12:40:01 |

US3592229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:21:23

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-08-22T07:39:50', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '6206a17d-f14a-40f1-bbe9-8d0591de7194' | System | 22 Aug 2020 12:40:01 |
| User entered 'No (N)' | System | 22 Aug 2020 12:40:01 |

US3592229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-08-22T07:39:53', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '6206a17d-f14a-40f1-bbe9-8d0591de7194' | System | 22 Aug 2020 12:40:01 |
| User entered 'No (N)' | System | 22 Aug 2020 12:40:01 |

US3592229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:21:23

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-08-22T07:39:55', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '6206a17d-f14a-40f1-bbe9-8d0591de7194' | System | 22 Aug 2020 12:40:01 |
| User entered 'None (1)' | System | 22 Aug 2020 12:40:01 |

US3592229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:21:23

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-08-22T07:39:58', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '6206a17d-f14a-40f1-bbe9-8d0591de7194' | System | 22 Aug 2020 12:40:01 |
| User entered '22 Aug 2020 07:39' | System | 22 Aug 2020 12:40:01 |

US3592229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:21:23

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| User entered '21 Aug 2020 12:00' | System | 18 Aug 2020 23:31:01 |

US3592229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:21:23

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| User entered '22 Aug 2020 11:59' | System | 18 Aug 2020 23:31:01 |

US3592229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:21:23

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| Data entry locked. | System | 18 Aug 2020 23:31:01 |
| User entered 'Day 5' | System | 18 Aug 2020 23:31:01 |

US3592229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:21:23

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-08-23T08:50:46', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: 'b744c115-3017-4ed8-84a2-4ed000f6b3cc' | System | 23 Aug 2020 13:51:06 |
| User entered 'None (1)' | System | 23 Aug 2020 13:51:06 |

US3592229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:21:23

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-08-23T08:50:48', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: 'b744c115-3017-4ed8-84a2-4ed000f6b3cc' | System | 23 Aug 2020 13:51:06 |
| User entered 'No (N)' | System | 23 Aug 2020 13:51:06 |

US3592229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-08-23T08:50:53', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: 'b744c115-3017-4ed8-84a2-4ed000f6b3cc' | System | 23 Aug 2020 13:51:06 |
| User entered 'No (N)' | System | 23 Aug 2020 13:51:06 |

US3592229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:21:23

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-08-23T08:50:59', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: 'b744c115-3017-4ed8-84a2-4ed000f6b3cc' | System | 23 Aug 2020 13:51:06 |
| User entered 'None (1)' | System | 23 Aug 2020 13:51:06 |

US3592229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:21:23

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-08-23T08:51:02', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: 'b744c115-3017-4ed8-84a2-4ed000f6b3cc' User entered '23 Aug 2020 08:51' | System | 23 Aug 2020 13:51:06 |
| | System | 23 Aug 2020 13:51:06 |

US3592229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:21:23

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| User entered '22 Aug 2020 12:00' | System | 18 Aug 2020 23:31:01 |

US3592229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:21:23

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| User entered '23 Aug 2020 11:59' | System | 18 Aug 2020 23:31:01 |

US3592229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:21:23

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| Data entry locked. | System | 18 Aug 2020 23:31:01 |
| User entered 'Day 6' | System | 18 Aug 2020 23:31:01 |

US3592229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:21:23

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-08-23T14:20:50', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '5086a36b-3869-4c98-8e05-ea499a51fc13' | System | 23 Aug 2020 19:21:06 |
| User entered 'None (1)' | System | 23 Aug 2020 19:21:06 |

US3592229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:21:23

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-08-23T14:20:52', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '5086a36b-3869-4c98-8e05-ea499a51fc13' | System | 23 Aug 2020 19:21:06 |
| User entered 'No (N)' | System | 23 Aug 2020 19:21:06 |

US3592229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-08-23T14:20:55', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '5086a36b-3869-4c98-8e05-ea499a51fc13' | System | 23 Aug 2020 19:21:06 |
| User entered 'No (N)' | System | 23 Aug 2020 19:21:06 |

US3592229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:21:23

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-08-23T14:20:56', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '5086a36b-3869-4c98-8e05-ea499a51fc13' | System | 23 Aug 2020 19:21:06 |
| User entered 'None (1)' | System | 23 Aug 2020 19:21:06 |

US3592229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:21:23

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-08-23T14:21:04', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '5086a36b-3869-4c98-8e05-ea499a51fc13' User entered '23 Aug 2020 14:21' | System | 23 Aug 2020 19:21:06 |
| | System | 23 Aug 2020 19:21:06 |

US3592229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:21:23

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| User entered '23 Aug 2020 12:00' | System | 18 Aug 2020 23:31:01 |

US3592229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:21:23

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| User entered '24 Aug 2020 11:59' | System | 18 Aug 2020 23:31:01 |

US3592229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:21:23

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| Data entry locked. | System | 18 Aug 2020 23:31:01 |
| User entered 'Day 7' | System | 18 Aug 2020 23:31:01 |

US3592229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:21:23

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-08-24T15:50:26', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: 'f3f9e1a3-9774-42ec-b29b-354b111be48f' User entered 'None (1)' | System | 24 Aug 2020 20:50:56 |
| | System | 24 Aug 2020 20:50:56 |

US3592229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:21:23

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-08-24T15:50:29', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: 'f3f9e1a3-9774-42ec-b29b-354b111be48f' User entered 'No (N)' | System | 24 Aug 2020 20:50:56 |
| | System | 24 Aug 2020 20:50:56 |

US3592229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-08-24T15:50:31', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: 'f3f9e1a3-9774-42ec-b29b-354b111be48f' User entered 'No (N)' | System | 24 Aug 2020 20:50:56 |
| | System | 24 Aug 2020 20:50:56 |

US3592229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:21:23

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-08-24T15:50:33', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: 'f3f9e1a3-9774-42ec-b29b-354b111be48f' User entered 'None (1)' | System | 24 Aug 2020 20:50:56 |
| | System | 24 Aug 2020 20:50:56 |

US3592229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:21:23

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-08-24T15:50:35', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: 'f3f9e1a3-9774-42ec-b29b-354b111be48f' User entered '24 Aug 2020 15:50' | System | 24 Aug 2020 20:50:56 |
| | System | 24 Aug 2020 20:50:56 |

US3592229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:21:23

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| User entered '24 Aug 2020 12:00' | System | 18 Aug 2020 23:31:01 |

US3592229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:21:23

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| User entered '25 Aug 2020 11:59' | System | 18 Aug 2020 23:31:01 |

US3592229

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:21:23

TIMEPOINT

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| Data entry locked. | System | 18 Aug 2020 23:31:01 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 18 Aug 2020 23:31:01 |

US3592229

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:21:23

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-08-18T19:01:27', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: 'ee679dc5-100c-48be-92fb-7e6ae0bda7d2' User entered 'None (0)' | System | 19 Aug 2020 00:02:00 |
| | System | 19 Aug 2020 00:02:00 |

US3592229

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:21:23

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-08-18T19:01:29', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: 'ee679dc5-100c-48be-92fb-7e6ae0bda7d2' | System | 19 Aug 2020 00:02:00 |
| User entered 'None (0)' | System | 19 Aug 2020 00:02:00 |

US3592229

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:21:23

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-08-18T19:01:36', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: 'ee679dc5-100c-48be-92fb-7e6ae0bda7d2' | System | 19 Aug 2020 00:02:00 |
| User entered 'None (0)' | System | 19 Aug 2020 00:02:00 |

US3592229

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:21:23

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-08-18T19:01:40', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: 'ee679dc5-100c-48be-92fb-7e6ae0bda7d2' User entered 'None (0)' | System | 19 Aug 2020 00:02:00 |
| | System | 19 Aug 2020 00:02:00 |

US3592229

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:21:23

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-08-18T19:01:43', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: 'ee679dc5-100c-48be-92fb-7e6ae0bda7d2' | System | 19 Aug 2020 00:02:00 |
| User entered 'None (0)' | System | 19 Aug 2020 00:02:00 |

US3592229

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:21:23

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-08-18T19:01:47', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: 'ee679dc5-100c-48be-92fb-7e6ae0bda7d2' | System | 19 Aug 2020 00:02:00 |
| User entered 'None (0)' | System | 19 Aug 2020 00:02:00 |

US3592229

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-08-18T19:01:55', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: 'ee679dc5-100c-48be-92fb-7e6ae0bda7d2' | System | 19 Aug 2020 00:02:00 |
| User entered 'No (N)' | System | 19 Aug 2020 00:02:00 |

US3592229

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:21:23

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-08-18T19:01:58', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: 'ee679dc5-100c-48be-92fb-7e6ae0bda7d2' | System | 19 Aug 2020 00:02:00 |
| User entered '18 Aug 2020 19:01' | System | 19 Aug 2020 00:02:00 |

US3592229

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:21:23

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| User entered '18 Aug 2020 18:46' | System | 18 Aug 2020 23:31:01 |

US3592229

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:21:23

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| User entered '18 Aug 2020 21:16' | System | 18 Aug 2020 23:31:01 |

US3592229

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:21:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| Data entry locked. | System | 18 Aug 2020 23:31:01 |
| User entered 'Day 1, after vaccination (at home)' | System | 18 Aug 2020 23:31:01 |

US3592229

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:21:23

HEADACHE

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-08-19T06:17:49', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '1d7a1462-9b1e-4db0-9680-58bdc35e3aa' User entered 'None (0)' | System | 19 Aug 2020 11:18:18 |
| | System | 19 Aug 2020 11:18:18 |

US3592229

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:21:23

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-08-19T06:17:53', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '1d7a1462-9b1e-4db0-9680-58bddc35e3aa' User entered 'None (0)' | System | 19 Aug 2020 11:18:18 |
| | System | 19 Aug 2020 11:18:18 |

US3592229

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:21:23

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-08-19T06:17:56', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '1d7a1462-9b1e-4db0-9680-58bddc35e3aa' User entered 'None (0)' | System | 19 Aug 2020 11:18:18 |
| | System | 19 Aug 2020 11:18:18 |

US3592229

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:21:23

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-08-19T06:18:05', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '1d7a1462-9b1e-4db0-9680-58bddc35e3aa' User entered 'None (0)' | System | 19 Aug 2020 11:18:18 |
| | System | 19 Aug 2020 11:18:18 |

US3592229

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:21:23

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-08-19T06:18:08', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '1d7a1462-9b1e-4db0-9680-58bddc35e3aa' User entered 'None (0)' | System | 19 Aug 2020 11:18:18 |
| | System | 19 Aug 2020 11:18:18 |

US3592229

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:21:23

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-08-19T06:18:10', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '1d7a1462-9b1e-4db0-9680-58bddc35e3aa' User entered 'None (0)' | System | 19 Aug 2020 11:18:18 |
| | System | 19 Aug 2020 11:18:18 |

US3592229

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-08-19T06:18:14', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '1d7a1462-9b1e-4db0-9680-58bddc35e3aa' | System | 19 Aug 2020 11:18:18 |
| User entered 'No (N)' | System | 19 Aug 2020 11:18:18 |

US3592229

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:21:23

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-08-19T06:18:16', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '1d7a1462-9b1e-4db0-9680-58bdc35e3aa' User entered '19 Aug 2020 06:18' | System | 19 Aug 2020 11:18:18 |
| | System | 19 Aug 2020 11:18:18 |

US3592229

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:21:23

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| User entered '18 Aug 2020 22:11' | System | 18 Aug 2020 23:31:01 |

US3592229

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:21:23

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| User entered '19 Aug 2020 11:59' | System | 18 Aug 2020 23:31:01 |

US3592229

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:21:23

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| Data entry locked. | System | 18 Aug 2020 23:31:01 |
| User entered 'Day 2' | System | 18 Aug 2020 23:31:01 |

US3592229

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:21:23

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-08-19T15:52:02', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '206c8fd4-0d3c-4a3a-a0ac-9849b61bf93e' User entered 'None (0)' | System | 19 Aug 2020 20:52:57 |
| | System | 19 Aug 2020 20:52:57 |

US3592229

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:21:23

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-08-19T15:52:09', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '206c8fd4-0d3c-4a3a-a0ac-9849b61bf93e' User entered 'None (0)' | System | 19 Aug 2020 20:52:57 |
| | System | 19 Aug 2020 20:52:57 |

US3592229

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:21:23

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-08-19T15:52:33', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '206c8fd4-0d3c-4a3a-a0ac-9849b61bf93e' | System | 19 Aug 2020 20:52:57 |
| User entered 'No interference with activity (1)' | System | 19 Aug 2020 20:52:57 |

US3592229

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:21:23

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-08-19T15:52:36', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '206c8fd4-0d3c-4a3a-a0ac-9849b61bf93e' | System | 19 Aug 2020 20:52:57 |
| User entered 'No interference with activity (1)' | System | 19 Aug 2020 20:52:57 |

US3592229

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:21:23

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-08-19T15:52:39', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '206c8fd4-0d3c-4a3a-a0ac-9849b61bf93e' User entered 'None (0)' | System | 19 Aug 2020 20:52:57 |
| | System | 19 Aug 2020 20:52:57 |

US3592229

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:21:23

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-08-19T15:52:41', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '206c8fd4-0d3c-4a3a-a0ac-9849b61bf93e' User entered 'None (0)' | System | 19 Aug 2020 20:52:57 |
| | System | 19 Aug 2020 20:52:57 |

US3592229

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-08-19T15:52:45', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '206c8fd4-0d3c-4a3a-a0ac-9849b61bf93e' User entered 'No (N)' | System | 19 Aug 2020 20:52:57 |
| | System | 19 Aug 2020 20:52:57 |

US3592229

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:21:23

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-08-19T15:52:55', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '206c8fd4-0d3c-4a3a-a0ac-9849b61bf93e' | System | 19 Aug 2020 20:52:57 |
| User entered '19 Aug 2020 15:52' | System | 19 Aug 2020 20:52:57 |

US3592229

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:21:23

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| User entered '19 Aug 2020 12:00' | System | 18 Aug 2020 23:31:01 |

US3592229

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:21:23

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| User entered '20 Aug 2020 11:59' | System | 18 Aug 2020 23:31:01 |

US3592229

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:21:23

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| Data entry locked. | System | 18 Aug 2020 23:31:01 |
| User entered 'Day 3' | System | 18 Aug 2020 23:31:01 |

US3592229

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:21:23

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-08-21T07:18:59', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '4fe3d43d-7595-4ed0-8ea3-49f89285521f' User entered 'None (0)' | System | 21 Aug 2020 12:19:21 |
| | System | 21 Aug 2020 12:19:21 |

US3592229

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:21:23

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-08-21T07:19:01', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '4fe3d43d-7595-4ed0-8ea3-49f89285521f' User entered 'None (0)' | System | 21 Aug 2020 12:19:21 |
| | System | 21 Aug 2020 12:19:21 |

US3592229

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:21:23

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-08-21T07:19:03', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '4fe3d43d-7595-4ed0-8ea3-49f89285521f' User entered 'None (0)' | System | 21 Aug 2020 12:19:21 |
| | System | 21 Aug 2020 12:19:21 |

US3592229

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:21:23

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-08-21T07:19:06', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '4fe3d43d-7595-4ed0-8ea3-49f89285521f' User entered 'None (0)' | System | 21 Aug 2020 12:19:21 |
| | System | 21 Aug 2020 12:19:21 |

US3592229

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:21:23

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-08-21T07:19:08', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '4fe3d43d-7595-4ed0-8ea3-49f89285521f' User entered 'None (0)' | System | 21 Aug 2020 12:19:21 |
| | System | 21 Aug 2020 12:19:21 |

US3592229

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:21:23

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-08-21T07:19:10', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '4fe3d43d-7595-4ed0-8ea3-49f89285521f' User entered 'None (0)' | System | 21 Aug 2020 12:19:21 |
| | System | 21 Aug 2020 12:19:21 |

US3592229

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-08-21T07:19:15', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '4fe3d43d-7595-4ed0-8ea3-49f89285521f' User entered 'No (N)' | System | 21 Aug 2020 12:19:21 |
| | System | 21 Aug 2020 12:19:21 |

US3592229

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:21:23

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-08-21T07:19:18', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '4fe3d43d-7595-4ed0-8ea3-49f89285521f' User entered '21 Aug 2020 07:19' | System | 21 Aug 2020 12:19:21 |
| | System | 21 Aug 2020 12:19:21 |

US3592229

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:21:23

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| User entered '20 Aug 2020 12:00' | System | 18 Aug 2020 23:31:01 |

US3592229

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:21:23

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| User entered '21 Aug 2020 11:59' | System | 18 Aug 2020 23:31:01 |

US3592229

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:21:23

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| Data entry locked. | System | 18 Aug 2020 23:31:01 |
| User entered 'Day 4' | System | 18 Aug 2020 23:31:01 |

US3592229

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:21:23

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-08-22T07:40:03', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '9a9bc302-70f8-4bd3-ac9d-c880be43b17f' User entered 'None (0)' | System | 22 Aug 2020 12:40:34 |
| | System | 22 Aug 2020 12:40:34 |

US3592229

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:21:23

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-08-22T07:40:06', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '9a9bc302-70f8-4bd3-ac9d-c880be43b17f' User entered 'None (0)' | System | 22 Aug 2020 12:40:34 |
| | System | 22 Aug 2020 12:40:34 |

US3592229

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:21:23

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-08-22T07:40:09', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '9a9bc302-70f8-4bd3-ac9d-c880be43b17f' User entered 'None (0)' | System | 22 Aug 2020 12:40:34 |
| | System | 22 Aug 2020 12:40:34 |

US3592229

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:21:23

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-08-22T07:40:12', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '9a9bc302-70f8-4bd3-ac9d-c880be43b17f' User entered 'None (0)' | System | 22 Aug 2020 12:40:34 |
| | System | 22 Aug 2020 12:40:34 |

US3592229

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:21:23

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-08-22T07:40:15', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '9a9bc302-70f8-4bd3-ac9d-c880be43b17f' User entered 'None (0)' | System | 22 Aug 2020 12:40:34 |
| | System | 22 Aug 2020 12:40:34 |

US3592229

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:21:23

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-08-22T07:40:17', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '9a9bc302-70f8-4bd3-ac9d-c880be43b17f' User entered 'None (0)' | System | 22 Aug 2020 12:40:34 |
| | System | 22 Aug 2020 12:40:34 |

US3592229

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-08-22T07:40:29', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '9a9bc302-70f8-4bd3-ac9d-c880be43b17f' User entered 'No (N)' | System | 22 Aug 2020 12:40:34 |
| | System | 22 Aug 2020 12:40:34 |

US3592229

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:21:23

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-08-22T07:40:32', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '9a9bc302-70f8-4bd3-ac9d-c880be43b17f' User entered '22 Aug 2020 07:40' | System | 22 Aug 2020 12:40:34 |
| | System | 22 Aug 2020 12:40:34 |

US3592229

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:21:23

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| User entered '21 Aug 2020 12:00' | System | 18 Aug 2020 23:31:01 |

US3592229

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:21:23

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| User entered '22 Aug 2020 11:59' | System | 18 Aug 2020 23:31:01 |

US3592229

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:21:23

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| Data entry locked. | System | 18 Aug 2020 23:31:01 |
| User entered 'Day 5' | System | 18 Aug 2020 23:31:01 |

US3592229

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:21:23

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-08-23T08:51:06', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '18112794-9666-44ad-aa0a-403d352db7ef' User entered 'None (0)' | System | 23 Aug 2020 13:52:08 |
| | System | 23 Aug 2020 13:52:08 |

US3592229

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:21:23

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-08-23T08:51:10', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '18112794-9666-44ad-aa0a-403d352db7ef' User entered 'None (0)' | System | 23 Aug 2020 13:52:08 |
| | System | 23 Aug 2020 13:52:08 |

US3592229

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:21:23

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-08-23T08:51:26', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '18112794-9666-44ad-aa0a-403d352db7ef' User entered 'None (0)' | System | 23 Aug 2020 13:52:08 |
| | System | 23 Aug 2020 13:52:08 |

US3592229

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:21:23

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-08-23T08:51:31', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '18112794-9666-44ad-aa0a-403d352db7ef' User entered 'None (0)' | System | 23 Aug 2020 13:52:08 |
| | System | 23 Aug 2020 13:52:08 |

US3592229

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:21:23

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-08-23T08:51:34', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '18112794-9666-44ad-aa0a-403d352db7ef' User entered 'None (0)' | System | 23 Aug 2020 13:52:08 |
| | System | 23 Aug 2020 13:52:08 |

US3592229

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:21:23

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-08-23T08:51:37', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '18112794-9666-44ad-aa0a-403d352db7ef' User entered 'None (0)' | System | 23 Aug 2020 13:52:08 |
| | System | 23 Aug 2020 13:52:08 |

US3592229

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-08-23T08:51:54', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '18112794-9666-44ad-aa0a-403d352db7ef' User entered 'Yes (Y)' | System | 23 Aug 2020 13:52:08 |
| | System | 23 Aug 2020 13:52:08 |

US3592229

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:21:23

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-08-23T08:52:03', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '18112794-9666-44ad-aa0a-403d352db7ef' User entered '23 Aug 2020 08:52' | System | 23 Aug 2020 13:52:08 |
| | System | 23 Aug 2020 13:52:08 |

US3592229

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:21:23

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| User entered '22 Aug 2020 12:00' | System | 18 Aug 2020 23:31:01 |

US3592229

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:21:23

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| User entered '23 Aug 2020 11:59' | System | 18 Aug 2020 23:31:01 |

US3592229

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:21:23

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| Data entry locked. | System | 18 Aug 2020 23:31:01 |
| User entered 'Day 6' | System | 18 Aug 2020 23:31:01 |

US3592229

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:21:23

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-08-23T14:21:37', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '71d701d5-2ece-4e8d-b2dc-4ec8afe9345e' | System | 23 Aug 2020 19:22:41 |
| User entered 'Any use of prescription pain reliever or System prevents daily activity (3)' | | 23 Aug 2020 19:22:41 |

US3592229

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:21:23

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-08-23T14:21:46', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '71d701d5-2ece-4e8d-b2dc-4ec8afe9345e' User entered 'Significant; prevents daily activity (3)' | System | 23 Aug 2020 19:22:41 |

US3592229

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:21:23

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-08-23T14:21:55', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '71d701d5-2ece-4e8d-b2dc-4ec8afe9345e' | System | 23 Aug 2020 19:22:41 |
| User entered 'Some interference with activity (2)' | System | 23 Aug 2020 19:22:41 |

US3592229

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:21:23

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-08-23T14:22:00', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '71d701d5-2ece-4e8d-b2dc-4ec8afe9345e' | System | 23 Aug 2020 19:22:41 |
| User entered 'Some interference with activity (2)' | System | 23 Aug 2020 19:22:41 |

US3592229

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:21:23

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-08-23T14:22:04', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '71d701d5-2ece-4e8d-b2dc-4ec8afe9345e' User entered 'None (0)' | System | 23 Aug 2020 19:22:41 |
| | System | 23 Aug 2020 19:22:41 |

US3592229

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:21:23

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-08-23T14:22:22', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '71d701d5-2ece-4e8d-b2dc-4ec8afe9345e' | System | 23 Aug 2020 19:22:41 |
| User entered 'Some interference with activity not requiring medical attention (2)' | System | 23 Aug 2020 19:22:41 |

US3592229

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-08-23T14:22:31', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '71d701d5-2ece-4e8d-b2dc-4ec8afe9345e' User entered 'Yes (Y)' | System | 23 Aug 2020 19:22:41 |
| | System | 23 Aug 2020 19:22:41 |

US3592229

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:21:23

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-08-23T14:22:39', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '71d701d5-2ece-4e8d-b2dc-4ec8afe9345e' User entered '23 Aug 2020 14:22' | System | 23 Aug 2020 19:22:41 |
| | System | 23 Aug 2020 19:22:41 |

US3592229

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:21:23

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| User entered '23 Aug 2020 12:00' | System | 18 Aug 2020 23:31:01 |

US3592229

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:21:23

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| User entered '24 Aug 2020 11:59' | System | 18 Aug 2020 23:31:01 |

US3592229

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:21:23

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| Data entry locked. | System | 18 Aug 2020 23:31:01 |
| User entered 'Day 7' | System | 18 Aug 2020 23:31:01 |

US3592229

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:21:23

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-08-24T15:50:40', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '7762268e-98d8-43df-8e4a-a397940f828a' User entered 'None (0)' | System | 24 Aug 2020 20:50:58 |
| | System | 24 Aug 2020 20:50:58 |

US3592229

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:21:23

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-08-24T15:50:42', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '7762268e-98d8-43df-8e4a-a397940f828a' User entered 'None (0)' | System | 24 Aug 2020 20:50:58 |
| | System | 24 Aug 2020 20:50:58 |

US3592229

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:21:23

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-08-24T15:50:44', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '7762268e-98d8-43df-8e4a-a397940f828a' User entered 'None (0)' | System | 24 Aug 2020 20:50:58 |
| | System | 24 Aug 2020 20:50:58 |

US3592229

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:21:23

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-08-24T15:50:45', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '7762268e-98d8-43df-8e4a-a397940f828a' User entered 'None (0)' | System | 24 Aug 2020 20:50:58 |
| | System | 24 Aug 2020 20:50:58 |

US3592229

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:21:23

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-08-24T15:50:47', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '7762268e-98d8-43df-8e4a-a397940f828a' User entered 'None (0)' | System | 24 Aug 2020 20:50:58 |
| | System | 24 Aug 2020 20:50:58 |

US3592229

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:21:23

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-08-24T15:50:48', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '7762268e-98d8-43df-8e4a-a397940f828a' User entered 'None (0)' | System | 24 Aug 2020 20:50:58 |
| | System | 24 Aug 2020 20:50:58 |

US3592229

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-08-24T15:50:52', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '7762268e-98d8-43df-8e4a-a397940f828a' User entered 'No (N)' | System | 24 Aug 2020 20:50:58 |
| | System | 24 Aug 2020 20:50:58 |

US3592229

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:21:23

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-08-24T15:50:54', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '7762268e-98d8-43df-8e4a-a397940f828a' User entered '24 Aug 2020 15:50' | System | 24 Aug 2020 20:50:58 |
| | System | 24 Aug 2020 20:50:58 |

US3592229

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:21:23

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| User entered '24 Aug 2020 12:00' | System | 18 Aug 2020 23:31:01 |

US3592229

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:21:23

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| User entered '25 Aug 2020 11:59' | System | 18 Aug 2020 23:31:01 |

US3592229

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:21:23

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:30:20 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 08 Sep 2020 23:02:44 |

US3592229

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:21:23

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:30:20 |
| User entered '26 Aug 2020' | (b) (4) (b) (4), (b) (6) | 08 Sep 2020 23:02:44 |

US3592229

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:21:23

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:30:20 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4) (b) (4), (b) (6) | 08 Sep 2020 23:02:44 |

US3592229

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:21:23

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:30:20 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 08 Sep 2020 23:02:44 |

US3592229

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:21:23

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:30:20 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 08 Sep 2020 23:02:51 |

US3592229

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:21:23

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User entered 'l' | System | 08 Sep 2020 23:02:51 |

US3592229

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:21:23

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:30:20 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 08 Sep 2020 23:03:56 |

US3592229

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:21:23

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:30:20 |
| User entered '1 Sep 2020' | (b) (4) (b) (4), (b) (6) | 08 Sep 2020 23:03:56 |

US3592229

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:21:23

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:30:20 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4) (b) (4), (b) (6) | 08 Sep 2020 23:03:56 |

US3592229

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:21:23

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:30:20 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 08 Sep 2020 23:03:56 |

US3592229

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:21:23

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:30:20 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 08 Sep 2020 23:04:06 |

US3592229

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:21:23

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User entered 'l' | System | 08 Sep 2020 23:04:06 |

US3592229

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:21:23

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:30:20 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 08 Sep 2020 23:05:09 |

US3592229

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:21:23

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:30:20 |
| User entered '8 Sep 2020' | (b) (4) (b) (4), (b) (6) | 08 Sep 2020 23:05:09 |

US3592229

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:21:23

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:30:20 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4) (b) (4), (b) (6) | 08 Sep 2020 23:05:09 |

US3592229

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:21:23

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:30:20 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 08 Sep 2020 23:05:09 |

US3592229

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:21:23

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:30:20 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 08 Sep 2020 23:05:15 |

US3592229

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:21:23

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User entered 'l' | System | 08 Sep 2020 23:05:15 |

US3592229

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:21:23

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:00:40 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 15 Sep 2020 16:15:11 |

US3592229

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:00:40 |
| User entered '15 Sep 2020' | (b) (4) (b) (4), (b) (6) | 15 Sep 2020 16:15:11 |

US3592229

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:21:23

[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 10:26:11 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:00:40 |
| User entered 'Home (Home)' | (b) (4) (b) (4), (b) (6) | 15 Sep 2020 16:15:11 |

US3592229

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:21:23

[Folder OID](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User entered 'VISIT2' | System | 15 Sep 2020 16:15:11 |

US3592229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:21:23

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User accepted default value 'Pre-Dose (PREDOSE)' | (b) (4), (b) (6) | 15 Sep 2020 16:21:51 |

US3592229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:21:23

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:00:40 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 15 Sep 2020 16:21:51 |

US3592229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:21:23

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:00:40 |
| User entered '15 Sep 2020' | (b) (4) (b) (4), (b) (6) | 15 Sep 2020 16:21:51 |

US3592229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:00:40 |
| User entered '7:19' | (b) (4) (b) (4), (b) (6) | 15 Sep 2020 16:21:51 |

US3592229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|---------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User entered '15 Sep 2020 7:19' | System | 15 Sep 2020 16:21:51 |

US3592229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:21:23

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:00:40 |
| User entered '97.9' F | (b) (4) (b) (4), (b) (6) | 15 Sep 2020 16:21:51 |

US3592229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:21:23

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:00:40 |
| User entered 'Oral (Oral)' | (b) (4) (b) (4), (b) (6) | 15 Sep 2020 16:21:51 |

US3592229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:21:23

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:00:40 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 15 Sep 2020 16:21:51 |

US3592229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:21:23

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:00:40 |
| User entered '74' | (b) (4) (b) (4), (b) (6) | 15 Sep 2020 16:21:51 |

US3592229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:21:23

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User entered 'bpm' | System | 15 Sep 2020 16:21:51 |

US3592229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:00:40 |
| User entered '16' | (b) (4) (b) (4), (b) (6) | 15 Sep 2020 16:21:51 |

US3592229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:21:23

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User entered 'breaths/min' | System | 15 Sep 2020 16:21:51 |

US3592229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:21:23

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:00:40 |
| User entered '128' | (b) (4) (b) (4), (b) (6) | 15 Sep 2020 16:21:51 |

US3592229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:21:23

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User entered 'mmHg' | System | 15 Sep 2020 16:21:51 |

US3592229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:21:23

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:00:40 |
| User entered '83' | (b) (4) (b) (4), (b) (6) | 15 Sep 2020 16:21:51 |

US3592229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:21:23

Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User entered 'mmHg' | System | 15 Sep 2020 16:21:51 |

US3592229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:21:23

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User accepted default value 'Post-Dose (POSTDOSE)' | (b) (4), (b) (6) | 15 Sep 2020 16:21:51 |

US3592229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:21:23

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:00:40 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 15 Sep 2020 16:21:51 |

US3592229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:21:23

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:00:40 |
| User entered '15 Sep 2020' | (b) (4) (b) (4), (b) (6) | 15 Sep 2020 16:21:51 |

US3592229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:00:40 |
| User entered '8:38' | (b) (4) (b) (4), (b) (6) | 15 Sep 2020 16:21:51 |

US3592229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|---------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User entered '15 Sep 2020 8:38' | System | 15 Sep 2020 16:21:51 |

US3592229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:21:23

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:00:40 |
| User entered '97.7' F | (b) (4) (b) (4), (b) (6) | 15 Sep 2020 16:21:51 |

US3592229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:21:23

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:00:40 |
| User entered 'Oral (Oral)' | (b) (4) (b) (4), (b) (6) | 15 Sep 2020 16:21:51 |

US3592229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:21:23

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:00:40 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 15 Sep 2020 16:21:51 |

US3592229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:21:23

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:00:40 |
| User entered '73' | (b) (4) (b) (4), (b) (6) | 15 Sep 2020 16:21:51 |

US3592229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:21:23

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User entered 'bpm' | System | 15 Sep 2020 16:21:51 |

US3592229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:00:40 |
| User entered '16' | (b) (4) (b) (4), (b) (6) | 15 Sep 2020 16:21:51 |

US3592229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:21:23

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User entered 'breaths/min' | System | 15 Sep 2020 16:21:51 |

US3592229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:21:23

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:00:40 |
| User entered '109' | (b) (4) (b) (4), (b) (6) | 15 Sep 2020 16:21:51 |

US3592229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:21:23

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User entered 'mmHg' | System | 15 Sep 2020 16:21:51 |

US3592229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:21:23

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:00:40 |
| User entered '77' | (b) (4) (b) (4), (b) (6) | 15 Sep 2020 16:21:51 |

US3592229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:21:23

Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User entered 'mmHg' | System | 15 Sep 2020 16:21:51 |

US3592229

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:21:23

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:00:40 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 15 Sep 2020 16:22:14 |

US3592229

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:21:23

Date of examination (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:00:40 |
| User entered '15 Sep 2020' | (b) (4) (b) (4), (b) (6) | 15 Sep 2020 16:22:14 |

US3592229

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:21:23

[Was study treatment given?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:00:40 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 15 Sep 2020 13:14:32 |

US3592229

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:21:23

[If No, reason not given](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:00:40 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 15 Sep 2020 13:14:32 |

US3592229

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:21:23

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 10:26:11 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:00:40 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 15 Sep 2020 13:14:32 |

US3592229

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:21:23

[What was the study treatment?](#)

| Audit | User | Time (GMT) |
|-------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User entered 'MRNA-1273 OR PLACEBO' | System | 15 Sep 2020 13:14:32 |

US3592229

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:21:23

What was the treatment date? (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:00:40 |
| User entered '15 Sep 2020' | (b) (4) (b) (4), (b) (6) | 15 Sep 2020 13:14:32 |

US3592229

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:00:40 |
| User entered '08:07' | (b) (4) (b) (4), (b) (6) | 15 Sep 2020 13:14:32 |

US3592229

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User entered '15 Sep 2020 08:07' | System | 15 Sep 2020 13:14:32 |

US3592229

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|------------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:00:40 |
| User entered 'Left Arm (LEFT ARM)' | (b) (4) (b) (4), (b) (6) | 15 Sep 2020 13:14:32 |

US3592229

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:21:23

What was the frequency of the study treatment dosing?

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User entered 'ONCE' | System | 15 Sep 2020 13:14:32 |

US3592229

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:21:23

What was the route of administration for the study treatment?

| Audit | User | Time (GMT) |
|------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User entered 'INTRAMUSCULAR' | System | 15 Sep 2020 13:14:32 |

US3592229

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:21:23

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:00:40 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 15 Sep 2020 16:23:10 |

US3592229

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:21:23

Collection date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:00:40 |
| User entered '15 Sep 2020' | (b) (4) (b) (4), (b) (6) | 15 Sep 2020 16:23:10 |

US3592229

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:21:23

Collection time (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:00:40 |
| User entered '7:39' | (b) (4) (b) (4), (b) (6) | 15 Sep 2020 16:23:10 |

US3592229

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|---------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User entered '15 Sep 2020 7:39' | System | 15 Sep 2020 16:23:10 |

US3592229

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 08:21:23

Collection date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:00:40 |
| User entered '15 Sep 2020' | (b) (4) (b) (4), (b) (6) | 15 Sep 2020 16:23:33 |

US3592229

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:21:23

[Lab Test](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)' | (b) (4), (b) (6) | 15 Sep 2020 16:23:33 |

US3592229

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:21:23

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:00:40 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 15 Sep 2020 16:23:33 |

US3592229

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:21:23

Collection time (00:00 - 23:59)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:00:40 |
| User entered '7:40' | (b) (4) (b) (4), (b) (6) | 15 Sep 2020 16:23:33 |

US3592229

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:21:23

Collection date and time (derived)

| Audit | User | Time (GMT) |
|---------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User entered '15 Sep 2020 7:40' | System | 15 Sep 2020 16:23:33 |

US3592229

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:21:23

[Lab Test](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)' | (b) (4), (b) (6) | 15 Sep 2020 16:23:33 |

US3592229

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:21:23

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:00:40 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 15 Sep 2020 16:23:33 |

US3592229

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:21:23

Collection time (00:00 - 23:59)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:00:40 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 15 Sep 2020 16:23:33 |

US3592229

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User entered empty. | System | 15 Sep 2020 16:23:33 |

US3592229

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:21:23

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:00:40 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 15 Sep 2020 16:23:50 |

US3592229

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:21:23

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User entered 'I' | System | 15 Sep 2020 16:23:50 |

US3592229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:21:23

TIMEPOINT

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| Data entry locked. | System | 15 Sep 2020 13:14:32 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 15 Sep 2020 13:14:32 |

US3592229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:21:23

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-09-15T08:37:44', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '0256302b-245a-4db9-9a4c-c010d2e9f865' User entered 'Yes (Y)' | System | 15 Sep 2020 13:38:01 |
| | System | 15 Sep 2020 13:38:01 |

US3592229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:21:23

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-09-15T08:37:49', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '0256302b-245a-4db9-9a4c-c010d2e9f865' User entered '97.7' | System | 15 Sep 2020 13:38:01 |
| | System | 15 Sep 2020 13:38:01 |

US3592229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-09-15T08:37:53', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '0256302b-245a-4db9-9a4c-c010d2e9f865' | System | 15 Sep 2020 13:38:01 |
| User entered 'No (N)' | System | 15 Sep 2020 13:38:01 |

US3592229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:21:23

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-09-15T08:37:56', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '0256302b-245a-4db9-9a4c-c010d2e9f865' User entered '15 Sep 2020 08:37' | System | 15 Sep 2020 13:38:01 |
| | System | 15 Sep 2020 13:38:01 |

US3592229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:21:23

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| User entered '15 Sep 2020 08:27' | System | 15 Sep 2020 13:14:32 |

US3592229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:21:23

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| User entered '15 Sep 2020 10:57' | System | 15 Sep 2020 13:14:32 |

US3592229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:21:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| Data entry locked. | System | 15 Sep 2020 13:14:32 |
| User entered 'Day 1, after vaccination (at home)' | System | 15 Sep 2020 13:14:32 |

US3592229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:21:23

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-09-15T16:22:40', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: 'bf4d1179-f584-41a3-b9a5-8ad1e66b070d' User entered 'Yes (Y)' | System | 15 Sep 2020 21:23:32 |
| | System | 15 Sep 2020 21:23:32 |

US3592229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:21:23

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-09-15T16:23:23', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: 'bf4d1179-f584-41a3-b9a5-8ad1e66b070d' User entered '97.5' | System | 15 Sep 2020 21:23:32 |
| | System | 15 Sep 2020 21:23:32 |

US3592229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-09-15T16:23:26', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: 'bf4d1179-f584-41a3-b9a5-8ad1e66b070d' User entered 'No (N)' | System | 15 Sep 2020 21:23:32 |
| | System | 15 Sep 2020 21:23:32 |

US3592229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:21:23

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-09-15T16:23:29', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: 'bf4d1179-f584-41a3-b9a5-8ad1e66b070d' User entered '15 Sep 2020 16:23' | System | 15 Sep 2020 21:23:32 |
| | System | 15 Sep 2020 21:23:32 |

US3592229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:21:23

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| User entered '15 Sep 2020 11:52' | System | 15 Sep 2020 13:14:32 |

US3592229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:21:23

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| User entered '16 Sep 2020 11:59' | System | 15 Sep 2020 13:14:32 |

US3592229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:21:23

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| Data entry locked. | System | 15 Sep 2020 13:14:32 |
| User entered 'Day 2' | System | 15 Sep 2020 13:14:32 |

US3592229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:21:23

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-09-16T18:20:06', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '4aeffcaa-8a99-42a2-9ac3-667f387fa9d7' | System | 16 Sep 2020 23:20:21 |
| User entered 'Yes (Y)' | System | 16 Sep 2020 23:20:21 |

US3592229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:21:23

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-09-16T18:20:11', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '4aeffcaa-8a99-42a2-9ac3-667f387fa9d7' User entered '97.7' | System | 16 Sep 2020 23:20:21 |
| | System | 16 Sep 2020 23:20:21 |

US3592229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-09-16T18:20:14', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '4aeffcaa-8a99-42a2-9ac3-667f387fa9d7' | System | 16 Sep 2020 23:20:21 |
| User entered 'No (N)' | System | 16 Sep 2020 23:20:21 |

US3592229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:21:23

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-09-16T18:20:16', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '4aeffcaa-8a99-42a2-9ac3-667f387fa9d7' | System | 16 Sep 2020 23:20:21 |
| User entered '16 Sep 2020 18:20' | System | 16 Sep 2020 23:20:21 |

US3592229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:21:23

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| User entered '16 Sep 2020 12:00' | System | 15 Sep 2020 13:14:32 |

US3592229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:21:23

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| User entered '17 Sep 2020 11:59' | System | 15 Sep 2020 13:14:32 |

US3592229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:21:23

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| Data entry locked. | System | 15 Sep 2020 13:14:32 |
| User entered 'Day 3' | System | 15 Sep 2020 13:14:32 |

US3592229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:21:23

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-09-17T17:38:25', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: 'db2aec5f-e1a8-4048-a4cf-63abec6cc0f7' | System | 17 Sep 2020 22:38:37 |
| User entered 'Yes (Y)' | System | 17 Sep 2020 22:38:37 |

US3592229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:21:23

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-09-17T17:38:29', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: 'db2aec5f-e1a8-4048-a4cf-63abec6cc0f7' User entered '97.5' | System | 17 Sep 2020 22:38:37 |
| | System | 17 Sep 2020 22:38:37 |

US3592229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-09-17T17:38:32', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: 'db2aec5f-e1a8-4048-a4cf-63abec6cc0f7' | System | 17 Sep 2020 22:38:37 |
| User entered 'No (N)' | System | 17 Sep 2020 22:38:37 |

US3592229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:21:23

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-09-17T17:38:35', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: 'db2aec5f-e1a8-4048-a4cf-63abec6cc0f7' | System | 17 Sep 2020 22:38:37 |
| User entered '17 Sep 2020 17:38' | System | 17 Sep 2020 22:38:37 |

US3592229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:21:23

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| User entered '17 Sep 2020 12:00' | System | 15 Sep 2020 13:14:32 |

US3592229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:21:23

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| User entered '18 Sep 2020 11:59' | System | 15 Sep 2020 13:14:32 |

US3592229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:21:23

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| Data entry locked. | System | 15 Sep 2020 13:14:32 |
| User entered 'Day 4' | System | 15 Sep 2020 13:14:32 |

US3592229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:21:23

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-09-18T17:15:47', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: 'a3a5494c-035f-4297-9b5f-dec0a0dae4bd' User entered 'Yes (Y)' | System | 18 Sep 2020 22:16:04 |
| | System | 18 Sep 2020 22:16:04 |

US3592229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:21:23

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-09-18T17:15:53', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: 'a3a5494c-035f-4297-9b5f-dec0a0dae4bd' User entered '97.8' | System | 18 Sep 2020 22:16:04 |
| | System | 18 Sep 2020 22:16:04 |

US3592229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-09-18T17:15:56', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: 'a3a5494c-035f-4297-9b5f-dec0a0dae4bd' User entered 'No (N)' | System | 18 Sep 2020 22:16:04 |
| | System | 18 Sep 2020 22:16:04 |

US3592229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:21:23

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-09-18T17:15:59', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: 'a3a5494c-035f-4297-9b5f-dec0a0dae4bd' User entered '18 Sep 2020 17:15' | System | 18 Sep 2020 22:16:04 |
| | System | 18 Sep 2020 22:16:04 |

US3592229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:21:23

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| User entered '18 Sep 2020 12:00' | System | 15 Sep 2020 13:14:32 |

US3592229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:21:23

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| User entered '19 Sep 2020 11:59' | System | 15 Sep 2020 13:14:32 |

US3592229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:21:23

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| Data entry locked. | System | 15 Sep 2020 13:14:32 |
| User entered 'Day 5' | System | 15 Sep 2020 13:14:32 |

US3592229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:21:23

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-09-19T18:00:42', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '1f8297d1-a828-484f-ad6c-3afc5d08982b' User entered 'Yes (Y)' | System | 19 Sep 2020 23:00:58 |
| | System | 19 Sep 2020 23:00:58 |

US3592229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:21:23

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-09-19T18:00:47', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '1f8297d1-a828-484f-ad6c-3afc5d08982b' User entered '97.7' | System | 19 Sep 2020 23:00:58 |
| | System | 19 Sep 2020 23:00:58 |

US3592229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-09-19T18:00:49', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '1f8297d1-a828-484f-ad6c-3afc5d08982b' User entered 'No (N)' | System | 19 Sep 2020 23:00:58 |
| | System | 19 Sep 2020 23:00:58 |

US3592229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:21:23

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-09-19T18:00:55', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '1f8297d1-a828-484f-ad6c-3afc5d08982b' User entered '19 Sep 2020 18:00' | System | 19 Sep 2020 23:00:58 |
| | System | 19 Sep 2020 23:00:58 |

US3592229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:21:23

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| User entered '19 Sep 2020 12:00' | System | 15 Sep 2020 13:14:32 |

US3592229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:21:23

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| User entered '20 Sep 2020 11:59' | System | 15 Sep 2020 13:14:32 |

US3592229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:21:23

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| Data entry locked. | System | 15 Sep 2020 13:14:32 |
| User entered 'Day 6' | System | 15 Sep 2020 13:14:32 |

US3592229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:21:23

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-09-20T17:00:25', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: 'b471ef24-eb4d-43b2-92de-89d8a9b187cc' | System | 20 Sep 2020 22:00:38 |
| User entered 'Yes (Y)' | System | 20 Sep 2020 22:00:38 |

US3592229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:21:23

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-09-20T17:00:30', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: 'b471ef24-eb4d-43b2-92de-89d8a9b187cc' User entered '97.8' | System | 20 Sep 2020 22:00:38 |
| | System | 20 Sep 2020 22:00:38 |

US3592229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-09-20T17:00:33', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: 'b471ef24-eb4d-43b2-92de-89d8a9b187cc' | System | 20 Sep 2020 22:00:38 |
| User entered 'No (N)' | System | 20 Sep 2020 22:00:38 |

US3592229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:21:23

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-09-20T17:00:35', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: 'b471ef24-eb4d-43b2-92de-89d8a9b187cc' | System | 20 Sep 2020 22:00:38 |
| User entered '20 Sep 2020 17:00' | System | 20 Sep 2020 22:00:38 |

US3592229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:21:23

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| User entered '20 Sep 2020 12:00' | System | 15 Sep 2020 13:14:32 |

US3592229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:21:23

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| User entered '21 Sep 2020 11:59' | System | 15 Sep 2020 13:14:32 |

US3592229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:21:23

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| Data entry locked. | System | 15 Sep 2020 13:14:32 |
| User entered 'Day 7' | System | 15 Sep 2020 13:14:32 |

US3592229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:21:23

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |

US3592229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:21:23

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |

US3592229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |

US3592229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |

US3592229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:21:23

To **PREVENT** pain or fever from occurring

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |

US3592229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:21:23

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |

US3592229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:21:23

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| User entered '21 Sep 2020 12:00' | System | 15 Sep 2020 13:14:32 |

US3592229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:21:23

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| User entered '22 Sep 2020 11:59' | System | 15 Sep 2020 13:14:32 |

US3592229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:21:23

TIMEPOINT

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| Data entry locked. | System | 15 Sep 2020 13:14:32 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 15 Sep 2020 13:14:32 |

US3592229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:21:23

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-09-15T08:37:59', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '98fd3c-1432-427a-902f-68d4c6ed45cc' | System | 15 Sep 2020 13:38:15 |
| User entered 'None (1)' | System | 15 Sep 2020 13:38:15 |

US3592229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:21:23

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-09-15T08:38:02', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '98fd3c-1432-427a-902f-68d4c6ed45cc' | System | 15 Sep 2020 13:38:15 |
| User entered 'No (N)' | System | 15 Sep 2020 13:38:15 |

US3592229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-09-15T08:38:04', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '98fd3c-1432-427a-902f-68d4c6ed45cc' | System | 15 Sep 2020 13:38:15 |
| User entered 'No (N)' | System | 15 Sep 2020 13:38:15 |

US3592229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:21:23

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-09-15T08:38:07', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '98fd3c-1432-427a-902f-68d4c6ed45cc' | System | 15 Sep 2020 13:38:15 |
| User entered 'None (1)' | System | 15 Sep 2020 13:38:15 |

US3592229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:21:23

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-09-15T08:38:09', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '98fd3c-1432-427a-902f-68d4c6ed45cc' | System | 15 Sep 2020 13:38:15 |
| User entered '15 Sep 2020 08:38' | System | 15 Sep 2020 13:38:15 |

US3592229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:21:23

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| User entered '15 Sep 2020 08:27' | System | 15 Sep 2020 13:14:32 |

US3592229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:21:23

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| User entered '15 Sep 2020 10:57' | System | 15 Sep 2020 13:14:32 |

US3592229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:21:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| Data entry locked. | System | 15 Sep 2020 13:14:32 |
| User entered 'Day 1, after vaccination (at home)' | System | 15 Sep 2020 13:14:32 |

US3592229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:21:23

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-09-15T16:23:33', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '7ec1769c-1e67-4a30-85e1-cd53c1e23dc1' User entered 'None (1)' | System | 15 Sep 2020 21:24:23 |
| | System | 15 Sep 2020 21:24:23 |

US3592229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:21:23

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-09-15T16:23:36', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '7ec1769c-1e67-4a30-85e1-cd53c1e23dc1' User entered 'No (N)' | System | 15 Sep 2020 21:24:23 |
| | System | 15 Sep 2020 21:24:23 |

US3592229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-09-15T16:23:39', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '7ec1769c-1e67-4a30-85e1-cd53c1e23dc1' User entered 'No (N)' | System | 15 Sep 2020 21:24:23 |
| | System | 15 Sep 2020 21:24:23 |

US3592229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:21:23

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-09-15T16:23:48', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '7ec1769c-1e67-4a30-85e1-cd53c1e23dc1' User entered 'None (1)' | System | 15 Sep 2020 21:24:23 |
| | System | 15 Sep 2020 21:24:23 |

US3592229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:21:23

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-09-15T16:23:51', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '7ec1769c-1e67-4a30-85e1-cd53c1e23dc1' User entered '15 Sep 2020 16:23' | System | 15 Sep 2020 21:24:23 |
| | System | 15 Sep 2020 21:24:23 |

US3592229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:21:23

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| User entered '15 Sep 2020 11:52' | System | 15 Sep 2020 13:14:32 |

US3592229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:21:23

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| User entered '16 Sep 2020 11:59' | System | 15 Sep 2020 13:14:32 |

US3592229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:21:23

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| Data entry locked. | System | 15 Sep 2020 13:14:32 |
| User entered 'Day 2' | System | 15 Sep 2020 13:14:32 |

US3592229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:21:23

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-09-16T18:20:20', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '328fba13-1f75-43b8-af14-e894e94e2735' | System | 16 Sep 2020 23:20:37 |
| User entered 'None (1)' | System | 16 Sep 2020 23:20:37 |

US3592229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:21:23

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-09-16T18:20:23', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '328fba13-1f75-43b8-af14-e894e94e2735' User entered 'No (N)' | System | 16 Sep 2020 23:20:37 |
| | System | 16 Sep 2020 23:20:37 |

US3592229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-09-16T18:20:25', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '328fba13-1f75-43b8-af14-e894e94e2735' User entered 'No (N)' | System | 16 Sep 2020 23:20:37 |
| | System | 16 Sep 2020 23:20:37 |

US3592229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:21:23

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-09-16T18:20:28', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '328fba13-1f75-43b8-af14-e894e94e2735' | System | 16 Sep 2020 23:20:37 |
| User entered 'None (1)' | System | 16 Sep 2020 23:20:37 |

US3592229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:21:23

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-09-16T18:20:30', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '328fba13-1f75-43b8-af14-e894e94e2735' User entered '16 Sep 2020 18:20' | System | 16 Sep 2020 23:20:37 |
| | System | 16 Sep 2020 23:20:37 |

US3592229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:21:23

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| User entered '16 Sep 2020 12:00' | System | 15 Sep 2020 13:14:32 |

US3592229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:21:23

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| User entered '17 Sep 2020 11:59' | System | 15 Sep 2020 13:14:32 |

US3592229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:21:23

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| Data entry locked. | System | 15 Sep 2020 13:14:32 |
| User entered 'Day 3' | System | 15 Sep 2020 13:14:32 |

US3592229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:21:23

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-09-17T17:38:39', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '45d1ec5a-e5be-43f6-9bc7-6ec94ce02887' | System | 17 Sep 2020 22:38:51 |
| User entered 'None (1)' | System | 17 Sep 2020 22:38:51 |

US3592229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:21:23

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-09-17T17:38:43', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '45d1ec5a-e5be-43f6-9bc7-6ec94ce02887' | System | 17 Sep 2020 22:38:51 |
| User entered 'No (N)' | System | 17 Sep 2020 22:38:51 |

US3592229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-09-17T17:38:45', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '45d1ec5a-e5be-43f6-9bc7-6ec94ce02887' | System | 17 Sep 2020 22:38:51 |
| User entered 'No (N)' | System | 17 Sep 2020 22:38:51 |

US3592229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:21:23

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-09-17T17:38:48', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '45d1ec5a-e5be-43f6-9bc7-6ec94ce02887' | System | 17 Sep 2020 22:38:51 |
| User entered 'None (1)' | System | 17 Sep 2020 22:38:51 |

US3592229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:21:23

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-09-17T17:38:50', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '45d1ec5a-e5be-43f6-9bc7-6ec94ce02887' User entered '17 Sep 2020 17:38' | System | 17 Sep 2020 22:38:51 |
| | System | 17 Sep 2020 22:38:51 |

US3592229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:21:23

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| User entered '17 Sep 2020 12:00' | System | 15 Sep 2020 13:14:32 |

US3592229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:21:23

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| User entered '18 Sep 2020 11:59' | System | 15 Sep 2020 13:14:32 |

US3592229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:21:23

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| Data entry locked. | System | 15 Sep 2020 13:14:32 |
| User entered 'Day 4' | System | 15 Sep 2020 13:14:32 |

US3592229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:21:23

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-09-18T17:16:02', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: 'deaf07da-939a-4df3-87c6-da4fbe7b3b55' | System | 18 Sep 2020 22:16:14 |
| User entered 'None (1)' | System | 18 Sep 2020 22:16:14 |

US3592229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:21:23

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-09-18T17:16:04', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: 'deaf07da-939a-4df3-87c6-da4fbe7b3b55' | System | 18 Sep 2020 22:16:14 |
| User entered 'No (N)' | System | 18 Sep 2020 22:16:14 |

US3592229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-09-18T17:16:07', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: 'deaf07da-939a-4df3-87c6-da4fbe7b3b55' | System | 18 Sep 2020 22:16:14 |
| User entered 'No (N)' | System | 18 Sep 2020 22:16:14 |

US3592229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:21:23

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-09-18T17:16:09', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: 'deaf07da-939a-4df3-87c6-da4fbe7b3b55' | System | 18 Sep 2020 22:16:14 |
| User entered 'None (1)' | System | 18 Sep 2020 22:16:14 |

US3592229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:21:23

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-09-18T17:16:11', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: 'deaf07da-939a-4df3-87c6-da4fbe7b3b55' | System | 18 Sep 2020 22:16:14 |
| User entered '18 Sep 2020 17:16' | System | 18 Sep 2020 22:16:14 |

US3592229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:21:23

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| User entered '18 Sep 2020 12:00' | System | 15 Sep 2020 13:14:32 |

US3592229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:21:23

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| User entered '19 Sep 2020 11:59' | System | 15 Sep 2020 13:14:32 |

US3592229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:21:23

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| Data entry locked. | System | 15 Sep 2020 13:14:32 |
| User entered 'Day 5' | System | 15 Sep 2020 13:14:32 |

US3592229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:21:23

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-09-19T18:00:58', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: 'b01c27c0-b253-426a-8b61-e649a89cd0d5' | System | 19 Sep 2020 23:01:12 |
| User entered 'None (1)' | System | 19 Sep 2020 23:01:12 |

US3592229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:21:23

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-09-19T18:01:01', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: 'b01c27c0-b253-426a-8b61-e649a89cd0d5' User entered 'No (N)' | System | 19 Sep 2020 23:01:12 |
| | System | 19 Sep 2020 23:01:12 |

US3592229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-09-19T18:01:03', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: 'b01c27c0-b253-426a-8b61-e649a89cd0d5' | System | 19 Sep 2020 23:01:12 |
| User entered 'No (N)' | System | 19 Sep 2020 23:01:12 |

US3592229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:21:23

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-09-19T18:01:05', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: 'b01c27c0-b253-426a-8b61-e649a89cd0d5' | System | 19 Sep 2020 23:01:12 |
| User entered 'None (1)' | System | 19 Sep 2020 23:01:12 |

US3592229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:21:23

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-09-19T18:01:08', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: 'b01c27c0-b253-426a-8b61-e649a89cd0d5' User entered '19 Sep 2020 18:01' | System | 19 Sep 2020 23:01:12 |
| | System | 19 Sep 2020 23:01:12 |

US3592229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:21:23

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| User entered '19 Sep 2020 12:00' | System | 15 Sep 2020 13:14:32 |

US3592229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:21:23

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| User entered '20 Sep 2020 11:59' | System | 15 Sep 2020 13:14:32 |

US3592229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:21:23

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| Data entry locked. | System | 15 Sep 2020 13:14:32 |
| User entered 'Day 6' | System | 15 Sep 2020 13:14:32 |

US3592229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:21:23

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-09-20T17:00:39', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '653d2240-028a-4bee-9441-524f29684f86' | System | 20 Sep 2020 22:00:51 |
| User entered 'None (1)' | System | 20 Sep 2020 22:00:51 |

US3592229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:21:23

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-09-20T17:00:42', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '653d2240-028a-4bee-9441-524f29684f86' | System | 20 Sep 2020 22:00:51 |
| User entered 'No (N)' | System | 20 Sep 2020 22:00:51 |

US3592229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-09-20T17:00:44', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '653d2240-028a-4bee-9441-524f29684f86' User entered 'No (N)' | System | 20 Sep 2020 22:00:51 |
| | System | 20 Sep 2020 22:00:51 |

US3592229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:21:23

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

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-09-20T17:00:46', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '653d2240-028a-4bee-9441-524f29684f86' User entered 'None (1)' | System | 20 Sep 2020 22:00:51 |
| | System | 20 Sep 2020 22:00:51 |

US3592229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:21:23

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-09-20T17:00:49', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '653d2240-028a-4bee-9441-524f29684f86' User entered '20 Sep 2020 17:00' | System | 20 Sep 2020 22:00:51 |
| | System | 20 Sep 2020 22:00:51 |

US3592229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:21:23

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| User entered '20 Sep 2020 12:00' | System | 15 Sep 2020 13:14:32 |

US3592229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:21:23

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| User entered '21 Sep 2020 11:59' | System | 15 Sep 2020 13:14:32 |

US3592229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:21:23

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| Data entry locked. | System | 15 Sep 2020 13:14:32 |
| User entered 'Day 7' | System | 15 Sep 2020 13:14:32 |

US3592229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:21:23

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

Please select one response below

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |

US3592229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:21:23

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |

US3592229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:21:23

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

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

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |

US3592229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |

US3592229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:21:23

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

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

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |

US3592229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:21:23

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

Please select one response below

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |

US3592229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:21:23

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |

US3592229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:21:23

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| User entered '21 Sep 2020 12:00' | System | 15 Sep 2020 13:14:32 |

US3592229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:21:23

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| User entered '22 Sep 2020 11:59' | System | 15 Sep 2020 13:14:32 |

US3592229

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:21:23

TIMEPOINT

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| Data entry locked. | System | 15 Sep 2020 13:14:32 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 15 Sep 2020 13:14:32 |

US3592229

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:21:23

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-09-15T08:38:12', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: 'fb7ad247-b1e3-4279-adfc-06859055e91b' User entered 'None (0)' | System | 15 Sep 2020 13:38:33 |
| | System | 15 Sep 2020 13:38:33 |

US3592229

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:21:23

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-09-15T08:38:14', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: 'fb7ad247-b1e3-4279-adfc-06859055e91b' User entered 'None (0)' | System | 15 Sep 2020 13:38:33 |
| | System | 15 Sep 2020 13:38:33 |

US3592229

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:21:23

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-09-15T08:38:16', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: 'fb7ad247-b1e3-4279-adfc-06859055e91b' User entered 'None (0)' | System | 15 Sep 2020 13:38:33 |
| | System | 15 Sep 2020 13:38:33 |

US3592229

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:21:23

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-09-15T08:38:20', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: 'fb7ad247-b1e3-4279-adfc-06859055e91b' User entered 'None (0)' | System | 15 Sep 2020 13:38:33 |
| | System | 15 Sep 2020 13:38:33 |

US3592229

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:21:23

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-09-15T08:38:22', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: 'fb7ad247-b1e3-4279-adfc-06859055e91b' User entered 'None (0)' | System | 15 Sep 2020 13:38:33 |
| | System | 15 Sep 2020 13:38:33 |

US3592229

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:21:23

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-09-15T08:38:23', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: 'fb7ad247-b1e3-4279-adfc-06859055e91b' User entered 'None (0)' | System | 15 Sep 2020 13:38:33 |
| | System | 15 Sep 2020 13:38:33 |

US3592229

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-09-15T08:38:28', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: 'fb7ad247-b1e3-4279-adfc-06859055e91b' User entered 'No (N)' | System | 15 Sep 2020 13:38:33 |
| | System | 15 Sep 2020 13:38:33 |

US3592229

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:21:23

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-09-15T08:38:31', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: 'fb7ad247-b1e3-4279-adfc-06859055e91b' User entered '15 Sep 2020 08:38' | System | 15 Sep 2020 13:38:33 |
| | System | 15 Sep 2020 13:38:33 |

US3592229

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:21:23

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| User entered '15 Sep 2020 08:27' | System | 15 Sep 2020 13:14:32 |

US3592229

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:21:23

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| User entered '15 Sep 2020 10:57' | System | 15 Sep 2020 13:14:32 |

US3592229

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:21:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| Data entry locked. | System | 15 Sep 2020 13:14:32 |
| User entered 'Day 1, after vaccination (at home)' | System | 15 Sep 2020 13:14:32 |

US3592229

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:21:23

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-09-15T16:23:56', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: 'd12b42f2-9ee5-4782-874a-70e70ca39dc9' User entered 'None (0)' | System | 15 Sep 2020 21:24:36 |
| | System | 15 Sep 2020 21:24:36 |

US3592229

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:21:23

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-09-15T16:24:02', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: 'd12b42f2-9ee5-4782-874a-70e70ca39dc9' | System | 15 Sep 2020 21:24:36 |
| User entered 'No interference with activity (1)' | System | 15 Sep 2020 21:24:36 |

US3592229

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:21:23

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-09-15T16:24:05', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: 'd12b42f2-9ee5-4782-874a-70e70ca39dc9' User entered 'None (0)' | System | 15 Sep 2020 21:24:36 |
| | System | 15 Sep 2020 21:24:36 |

US3592229

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:21:23

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-09-15T16:24:08', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: 'd12b42f2-9ee5-4782-874a-70e70ca39dc9' User entered 'None (0)' | System | 15 Sep 2020 21:24:36 |
| | System | 15 Sep 2020 21:24:36 |

US3592229

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:21:23

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-09-15T16:24:10', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: 'd12b42f2-9ee5-4782-874a-70e70ca39dc9' User entered 'None (0)' | System | 15 Sep 2020 21:24:36 |
| | System | 15 Sep 2020 21:24:36 |

US3592229

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:21:23

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-09-15T16:24:14', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: 'd12b42f2-9ee5-4782-874a-70e70ca39dc9' User entered 'None (0)' | System | 15 Sep 2020 21:24:36 |
| | System | 15 Sep 2020 21:24:36 |

US3592229

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-09-15T16:24:23', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: 'd12b42f2-9ee5-4782-874a-70e70ca39dc9' User entered 'No (N)' | System | 15 Sep 2020 21:24:36 |
| | System | 15 Sep 2020 21:24:36 |

US3592229

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:21:23

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-09-15T16:24:28', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: 'd12b42f2-9ee5-4782-874a-70e70ca39dc9' User entered '15 Sep 2020 16:24' | System | 15 Sep 2020 21:24:36 |
| | System | 15 Sep 2020 21:24:36 |

US3592229

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:21:23

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| User entered '15 Sep 2020 11:52' | System | 15 Sep 2020 13:14:32 |

US3592229

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:21:23

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| User entered '16 Sep 2020 11:59' | System | 15 Sep 2020 13:14:32 |

US3592229

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:21:23

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| Data entry locked. | System | 15 Sep 2020 13:14:32 |
| User entered 'Day 2' | System | 15 Sep 2020 13:14:32 |

US3592229

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:21:23

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-09-16T18:20:33', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: 'daa9f709-0342-4870-a473-0c843dbbaecd' User entered 'None (0)' | System | 16 Sep 2020 23:20:53 |
| | System | 16 Sep 2020 23:20:53 |

US3592229

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:21:23

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-09-16T18:20:36', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: 'daa9f709-0342-4870-a473-0c843dbbaecd' | System | 16 Sep 2020 23:20:53 |
| User entered 'No interference with activity (1)' | System | 16 Sep 2020 23:20:53 |

US3592229

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:21:23

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-09-16T18:20:38', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: 'daa9f709-0342-4870-a473-0c843dbbaecd' User entered 'None (0)' | System | 16 Sep 2020 23:20:53 |
| | System | 16 Sep 2020 23:20:53 |

US3592229

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:21:23

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-09-16T18:20:41', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: 'daa9f709-0342-4870-a473-0c843dbbaecd' User entered 'None (0)' | System | 16 Sep 2020 23:20:53 |
| | System | 16 Sep 2020 23:20:53 |

US3592229

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:21:23

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-09-16T18:20:43', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: 'daa9f709-0342-4870-a473-0c843dbbaecd' User entered 'None (0)' | System | 16 Sep 2020 23:20:53 |
| | System | 16 Sep 2020 23:20:53 |

US3592229

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:21:23

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-09-16T18:20:45', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: 'daa9f709-0342-4870-a473-0c843dbbaecd' User entered 'None (0)' | System | 16 Sep 2020 23:20:53 |
| | System | 16 Sep 2020 23:20:53 |

US3592229

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-09-16T18:20:47', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: 'daa9f709-0342-4870-a473-0c843dbbaecd' User entered 'No (N)' | System | 16 Sep 2020 23:20:53 |
| | System | 16 Sep 2020 23:20:53 |

US3592229

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:21:23

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-09-16T18:20:50', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: 'daa9f709-0342-4870-a473-0c843dbbaecd' User entered '16 Sep 2020 18:20' | System | 16 Sep 2020 23:20:53 |
| | System | 16 Sep 2020 23:20:53 |

US3592229

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:21:23

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| User entered '16 Sep 2020 12:00' | System | 15 Sep 2020 13:14:32 |

US3592229

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:21:23

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| User entered '17 Sep 2020 11:59' | System | 15 Sep 2020 13:14:32 |

US3592229

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:21:23

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| Data entry locked. | System | 15 Sep 2020 13:14:32 |
| User entered 'Day 3' | System | 15 Sep 2020 13:14:32 |

US3592229

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:21:23

HEADACHE

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-09-17T17:38:54', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '788ca773-41bd-42e6-979c-850bcd00a60' User entered 'None (0)' | System | 17 Sep 2020 22:39:14 |
| | System | 17 Sep 2020 22:39:14 |

US3592229

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:21:23

FATIGUE

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-09-17T17:38:57', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '788ca773-41bd-42e6-979c-850bcd00a60' User entered 'None (0)' | System | 17 Sep 2020 22:39:14 |
| | System | 17 Sep 2020 22:39:14 |

US3592229

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:21:23

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-09-17T17:39:00', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '788ca773-41bd-42e6-979c-850bcd00a60' | System | 17 Sep 2020 22:39:14 |
| User entered 'None (0)' | System | 17 Sep 2020 22:39:14 |

US3592229

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:21:23

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-09-17T17:39:02', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '788ca773-41bd-42e6-979c-850bcd00a60' User entered 'None (0)' | System | 17 Sep 2020 22:39:14 |
| | System | 17 Sep 2020 22:39:14 |

US3592229

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:21:23

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-09-17T17:39:04', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '788ca773-41bd-42e6-979c-850bcd00a60' User entered 'None (0)' | System | 17 Sep 2020 22:39:14 |
| | System | 17 Sep 2020 22:39:14 |

US3592229

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:21:23

CHILLS

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-09-17T17:39:06', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '788ca773-41bd-42e6-979c-850bcd00a60' | System | 17 Sep 2020 22:39:14 |
| User entered 'None (0)' | System | 17 Sep 2020 22:39:14 |

US3592229

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-09-17T17:39:08', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '788ca773-41bd-42e6-979c-850bcd00a60' | System | 17 Sep 2020 22:39:14 |
| User entered 'No (N)' | System | 17 Sep 2020 22:39:14 |

US3592229

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:21:23

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-09-17T17:39:11', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '788ca773-41bd-42e6-979c-850bcd00a60' | System | 17 Sep 2020 22:39:14 |
| User entered '17 Sep 2020 17:39' | System | 17 Sep 2020 22:39:14 |

US3592229

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:21:23

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| User entered '17 Sep 2020 12:00' | System | 15 Sep 2020 13:14:32 |

US3592229

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:21:23

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| User entered '18 Sep 2020 11:59' | System | 15 Sep 2020 13:14:32 |

US3592229

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:21:23

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| Data entry locked. | System | 15 Sep 2020 13:14:32 |
| User entered 'Day 4' | System | 15 Sep 2020 13:14:32 |

US3592229

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:21:23

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-09-18T17:16:15', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: 'ba449551-a063-4e50-bb09-95cb3d34d063' User entered 'None (0)' | System | 18 Sep 2020 22:16:37 |
| | System | 18 Sep 2020 22:16:37 |

US3592229

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:21:23

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-09-18T17:16:17', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: 'ba449551-a063-4e50-bb09-95cb3d34d063' User entered 'None (0)' | System | 18 Sep 2020 22:16:37 |
| | System | 18 Sep 2020 22:16:37 |

US3592229

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:21:23

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-09-18T17:16:19', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: 'ba449551-a063-4e50-bb09-95cb3d34d063' User entered 'None (0)' | System | 18 Sep 2020 22:16:37 |
| | System | 18 Sep 2020 22:16:37 |

US3592229

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:21:23

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-09-18T17:16:21', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: 'ba449551-a063-4e50-bb09-95cb3d34d063' User entered 'None (0)' | System | 18 Sep 2020 22:16:37 |
| | System | 18 Sep 2020 22:16:37 |

US3592229

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:21:23

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-09-18T17:16:23', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: 'ba449551-a063-4e50-bb09-95cb3d34d063' User entered 'None (0)' | System | 18 Sep 2020 22:16:37 |
| | System | 18 Sep 2020 22:16:37 |

US3592229

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:21:23

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-09-18T17:16:25', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: 'ba449551-a063-4e50-bb09-95cb3d34d063' User entered 'None (0)' | System | 18 Sep 2020 22:16:37 |
| | System | 18 Sep 2020 22:16:37 |

US3592229

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-09-18T17:16:30', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: 'ba449551-a063-4e50-bb09-95cb3d34d063' User entered 'No (N)' | System | 18 Sep 2020 22:16:37 |
| | System | 18 Sep 2020 22:16:37 |

US3592229

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:21:23

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-09-18T17:16:32', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: 'ba449551-a063-4e50-bb09-95cb3d34d063' | System | 18 Sep 2020 22:16:37 |
| User entered '18 Sep 2020 17:16' | System | 18 Sep 2020 22:16:37 |

US3592229

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:21:23

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| User entered '18 Sep 2020 12:00' | System | 15 Sep 2020 13:14:32 |

US3592229

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:21:23

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| User entered '19 Sep 2020 11:59' | System | 15 Sep 2020 13:14:32 |

US3592229

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:21:23

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| Data entry locked. | System | 15 Sep 2020 13:14:32 |
| User entered 'Day 5' | System | 15 Sep 2020 13:14:32 |

US3592229

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:21:23

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-09-19T18:01:12', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: 'f94cb026-44dc-4818-8559-b9c10153a282' | System | 19 Sep 2020 23:01:31 |
| User entered 'None (0)' | System | 19 Sep 2020 23:01:31 |

US3592229

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:21:23

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-09-19T18:01:14', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: 'f94cb026-44dc-4818-8559-b9c10153a282' User entered 'None (0)' | System | 19 Sep 2020 23:01:31 |
| | System | 19 Sep 2020 23:01:31 |

US3592229

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:21:23

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-09-19T18:01:16', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: 'f94cb026-44dc-4818-8559-b9c10153a282' User entered 'None (0)' | System | 19 Sep 2020 23:01:31 |
| | System | 19 Sep 2020 23:01:31 |

US3592229

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:21:23

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-09-19T18:01:18', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: 'f94cb026-44dc-4818-8559-b9c10153a282' User entered 'None (0)' | System | 19 Sep 2020 23:01:31 |
| | System | 19 Sep 2020 23:01:31 |

US3592229

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:21:23

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-09-19T18:01:20', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: 'f94cb026-44dc-4818-8559-b9c10153a282' User entered 'None (0)' | System | 19 Sep 2020 23:01:31 |
| | System | 19 Sep 2020 23:01:31 |

US3592229

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:21:23

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-09-19T18:01:22', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: 'f94cb026-44dc-4818-8559-b9c10153a282' User entered 'None (0)' | System | 19 Sep 2020 23:01:31 |
| | System | 19 Sep 2020 23:01:31 |

US3592229

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-09-19T18:01:27', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: 'f94cb026-44dc-4818-8559-b9c10153a282' | System | 19 Sep 2020 23:01:31 |
| User entered 'No (N)' | System | 19 Sep 2020 23:01:31 |

US3592229

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:21:23

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-09-19T18:01:30', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: 'f94cb026-44dc-4818-8559-b9c10153a282' User entered '19 Sep 2020 18:01' | System | 19 Sep 2020 23:01:31 |
| | System | 19 Sep 2020 23:01:31 |

US3592229

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:21:23

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| User entered '19 Sep 2020 12:00' | System | 15 Sep 2020 13:14:32 |

US3592229

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:21:23

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| User entered '20 Sep 2020 11:59' | System | 15 Sep 2020 13:14:32 |

US3592229

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:21:23

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| Data entry locked. | System | 15 Sep 2020 13:14:32 |
| User entered 'Day 6' | System | 15 Sep 2020 13:14:32 |

US3592229

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:21:23

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-09-20T17:00:52', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '5af32777-e779-4e52-aad8-e0822ab1a281' User entered 'None (0)' | System | 20 Sep 2020 22:01:13 |
| | System | 20 Sep 2020 22:01:13 |

US3592229

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:21:23

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-09-20T17:00:54', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '5af32777-e779-4e52-aad8-e0822ab1a281' User entered 'None (0)' | System | 20 Sep 2020 22:01:13 |
| | System | 20 Sep 2020 22:01:13 |

US3592229

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:21:23

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-09-20T17:00:56', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '5af32777-e779-4e52-aad8-e0822ab1a281' User entered 'None (0)' | System | 20 Sep 2020 22:01:13 |
| | System | 20 Sep 2020 22:01:13 |

US3592229

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:21:23

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-09-20T17:00:58', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '5af32777-e779-4e52-aad8-e0822ab1a281' User entered 'None (0)' | System | 20 Sep 2020 22:01:13 |
| | System | 20 Sep 2020 22:01:13 |

US3592229

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:21:23

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-09-20T17:01:00', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '5af32777-e779-4e52-aad8-e0822ab1a281' User entered 'None (0)' | System | 20 Sep 2020 22:01:13 |
| | System | 20 Sep 2020 22:01:13 |

US3592229

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:21:23

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-09-20T17:01:02', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '5af32777-e779-4e52-aad8-e0822ab1a281' User entered 'None (0)' | System | 20 Sep 2020 22:01:13 |
| | System | 20 Sep 2020 22:01:13 |

US3592229

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-09-20T17:01:09', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '5af32777-e779-4e52-aad8-e0822ab1a281' User entered 'No (N)' | System | 20 Sep 2020 22:01:13 |
| | System | 20 Sep 2020 22:01:13 |

US3592229

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:21:23

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-09-20T17:01:11', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '5af32777-e779-4e52-aad8-e0822ab1a281' User entered '20 Sep 2020 17:01' | System | 20 Sep 2020 22:01:13 |
| | System | 20 Sep 2020 22:01:13 |

US3592229

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:21:23

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| User entered '20 Sep 2020 12:00' | System | 15 Sep 2020 13:14:32 |

US3592229

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:21:23

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| User entered '21 Sep 2020 11:59' | System | 15 Sep 2020 13:14:32 |

US3592229

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:21:23

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| Data entry locked. | System | 15 Sep 2020 13:14:32 |
| User entered 'Day 7' | System | 15 Sep 2020 13:14:32 |

US3592229

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:21:23

HEADACHE

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |

US3592229

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:21:23

FATIGUE

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |

US3592229

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:21:23

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |

US3592229

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:21:23

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |

US3592229

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:21:23

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |

US3592229

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:21:23

CHILLS

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |

US3592229

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |

US3592229

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:21:23

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |

US3592229

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:21:23

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| User entered '21 Sep 2020 12:00' | System | 15 Sep 2020 13:14:32 |

US3592229

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:21:23

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| User entered '22 Sep 2020 11:59' | System | 15 Sep 2020 13:14:32 |

US3592229

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:21:23

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:30:20 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 25 Sep 2020 17:31:48 |

US3592229

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:21:23

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:30:20 |
| User entered '23 Sep 2020' | (b) (4) (b) (4), (b) (6) | 25 Sep 2020 17:31:48 |

US3592229

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:21:23

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:30:20 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4) (b) (4), (b) (6) | 25 Sep 2020 17:31:48 |

US3592229

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:21:23

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:30:20 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 25 Sep 2020 17:31:48 |

US3592229

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:21:23

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:30:20 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 25 Sep 2020 17:32:09 |

US3592229

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:21:23

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User entered 'l' | System | 25 Sep 2020 17:32:09 |

US3592229

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:21:23

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:00:40 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 01 Oct 2020 16:45:06 |

US3592229

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:21:23

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:00:40 |
| User entered '30 Sep 2020' | (b) (4) (b) (4), (b) (6) | 01 Oct 2020 16:45:06 |

US3592229

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:21:23

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:00:40 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4) (b) (4), (b) (6) | 01 Oct 2020 16:45:06 |

US3592229

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:21:23

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:00:40 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 01 Oct 2020 16:45:06 |

US3592229

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:21:23

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:00:40 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 01 Oct 2020 16:45:17 |

US3592229

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:21:23

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User entered 'l' | System | 01 Oct 2020 16:45:17 |

US3592229

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:21:23

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:00:40 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 06 Oct 2020 21:24:58 |

US3592229

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:21:23

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:00:40 |
| User entered '6 Oct 2020' | (b) (4) (b) (4), (b) (6) | 06 Oct 2020 21:24:58 |

US3592229

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:21:23

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:00:40 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4) (b) (4), (b) (6) | 06 Oct 2020 21:24:58 |

US3592229

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:21:23

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:00:40 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 06 Oct 2020 21:24:58 |

US3592229

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:21:23

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:00:40 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 06 Oct 2020 21:25:20 |

US3592229

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:21:23

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User entered 'l' | System | 06 Oct 2020 21:25:20 |

US3592229

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:21:23

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:00:40 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | (b) (4) | |
| | (b) (4), (b) (6) | 15 Oct 2020 19:45:08 |
| User closed query 'Data is required. Please complete.' (Site from System). | (b) (4), (b) (6) | 13 Oct 2020 08:04:46 |
| Query 'Data is required. Please complete.' answered with 'data was entered in error' (Site from System). | (b) (4), (b) (6) | 09 Oct 2020 22:35:11 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 09 Oct 2020 22:34:57 |
| User entered empty; reason for change Data Entry Error | (b) (4), (b) (6) | 09 Oct 2020 22:34:57 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 09 Oct 2020 14:31:11 |

US3592229

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:21:23

Visit date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:00:40 |
| User entered '15 Oct 2020' reason for change: Data Entry Error | (b) (4) (b) (4), (b) (6) | 15 Oct 2020 19:45:08 |
| User closed query 'Visit 3 Date is < 25 or > 35 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System). | (b) (4), (b) (6) | 14 Oct 2020 04:03:42 |
| User entered empty; reason for change Data Entry Error | (b) (4), (b) (6) | 09 Oct 2020 22:34:57 |
| Query 'Visit 3 Date is < 25 or > 35 days after Visit 2 vaccination. Please reconcile or confirm dates.' | (b) (4), (b) (6) | 09 Oct 2020 14:39:25 |
| answered with 'visit 2 and visit 3 were within 30 days of each other' (Site from System). | | |
| User opened query 'Visit 3 Date is < 25 or > 35 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System). | System | 09 Oct 2020 14:38:51 |
| User closed query 'Data entered is non-conformant. Please correct.' (Site from System). | System | 09 Oct 2020 14:38:51 |
| User entered '8 Oct 2020' reason for change: Data Entry Error | (b) (4), (b) (6) | 09 Oct 2020 14:38:51 |
| User opened query 'Data entered is non-conformant. Please correct.' (Site from System). | System | 09 Oct 2020 14:38:35 |
| User closed query 'Visit 3 Date is < 25 or > 35 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System). | System | 09 Oct 2020 14:38:35 |
| Query 'Visit 3 Date is < 25 or > 35 days after Visit 2 vaccination. Please reconcile or confirm dates.' | System | 09 Oct 2020 14:38:35 |
| answered by data change (Site from System). | | |
| User entered '8T Oct 2020' (non-conformant). | (b) (4), (b) (6) | 09 Oct 2020 14:38:35 |
| User opened query 'Visit 3 Date is < 25 or > 35 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System). | System | 09 Oct 2020 14:31:11 |
| User entered '8 Oct 2020' | (b) (4), (b) (6) | 09 Oct 2020 14:31:11 |

US3592229

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:21:23

[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 10:26:11 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:00:40 |
| User entered 'Clinic (Clinic)' reason for change: Data Entry Error | (b) (4) (b) (4), (b) (6) | 15 Oct 2020 19:45:08 |
| User entered empty; reason for change Data Entry Error | (b) (4), (b) (6) | 09 Oct 2020 22:34:57 |
| User entered 'Clinic (Clinic)' | (b) (4), (b) (6) | 09 Oct 2020 14:31:11 |

US3592229

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:21:23

[Folder OID](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User entered 'VISIT3' | System | 15 Oct 2020 19:45:08 |
| User entered empty. | System | 09 Oct 2020 22:34:57 |
| User entered 'VISIT3' | System | 09 Oct 2020 14:31:11 |

US3592229

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:21:23

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:00:40 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | (b) (4) | |
| | (b) (4), (b) (6) | 15 Oct 2020 19:46:39 |
| User closed query 'Data is required. Please complete.' (Site from System). | (b) (4), (b) (6) | 13 Oct 2020 08:05:31 |
| Query 'Data is required. Please complete.' answered with 'data was entered in error' (Site from System). | (b) (4), (b) (6) | 09 Oct 2020 22:36:44 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 09 Oct 2020 22:36:28 |
| User entered empty; reason for change Data Entry Error | (b) (4), (b) (6) | 09 Oct 2020 22:36:28 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 09 Oct 2020 14:33:58 |

US3592229

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:21:23

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:00:40 |
| User entered '15 Oct 2020' reason for change: Data Entry Error | (b) (4) (b) (4), (b) (6) | 15 Oct 2020 19:46:39 |
| User entered empty; reason for change Data Entry Error | (b) (4), (b) (6) | 09 Oct 2020 22:36:28 |
| User entered '8 Oct 2020' | (b) (4), (b) (6) | 09 Oct 2020 14:33:58 |

US3592229

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:00:40 |
| User entered '07:22' reason for change: Data Entry Error | (b) (4) (b) (4), (b) (6) | 15 Oct 2020 19:46:39 |
| User entered empty; reason for change Data Entry Error | (b) (4), (b) (6) | 09 Oct 2020 22:36:28 |
| User entered '16:05' | (b) (4), (b) (6) | 09 Oct 2020 14:33:58 |

US3592229

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User entered '15 Oct 2020 07:22' | System | 15 Oct 2020 19:46:39 |
| User entered empty. | System | 09 Oct 2020 22:36:28 |
| User entered '8 Oct 2020 16:05' | System | 09 Oct 2020 14:33:58 |

US3592229

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:21:23

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:00:40 |
| User entered '98.1' F reason for change: Data Entry Error | (b) (4) (b) (4), (b) (6) | 15 Oct 2020 19:46:39 |
| User entered empty; reason for change Data Entry Error | (b) (4), (b) (6) | 09 Oct 2020 22:36:28 |
| User closed query 'Data is required. Please provide.' (Site from System). | System | 09 Oct 2020 14:40:41 |
| Query 'Data is required. Please provide.' answered by data change (Site from System). | System | 09 Oct 2020 14:40:41 |
| User entered '98.0' F reason for change: Data Entry Error | (b) (4), (b) (6) | 09 Oct 2020 14:40:41 |
| User opened query 'Data is required. Please provide.' (Site from System). | System | 09 Oct 2020 14:33:58 |
| User entered empty. | (b) (4), (b) (6) | 09 Oct 2020 14:33:58 |

US3592229

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:21:23

[Route of measurement](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:00:40 |
| User entered 'Oral (Oral)' reason for change: Data Entry Error | (b) (4) (b) (4), (b) (6) | 15 Oct 2020 19:46:39 |
| User entered empty; reason for change Data Entry Error | (b) (4), (b) (6) | 09 Oct 2020 22:36:28 |
| User entered 'Oral (Oral)' | (b) (4), (b) (6) | 09 Oct 2020 14:33:58 |

US3592229

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:21:23

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:00:40 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 09 Oct 2020 14:33:58 |

US3592229

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:21:23

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:00:40 |
| User entered '71' reason for change: Data Entry Error | (b) (4) (b) (4), (b) (6) | 15 Oct 2020 19:46:39 |
| User entered empty; reason for change Data Entry Error | (b) (4), (b) (6) | 09 Oct 2020 22:36:28 |
| User entered '81' | (b) (4), (b) (6) | 09 Oct 2020 14:33:58 |

US3592229

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:21:23

[Pulse units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User entered 'bpm' | System | 15 Oct 2020 19:46:39 |
| User entered empty. | System | 09 Oct 2020 22:36:28 |
| User entered 'bpm' | System | 09 Oct 2020 14:33:58 |

US3592229

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:00:40 |
| User entered '16' reason for change: Data Entry Error | (b) (4) (b) (4), (b) (6) | 15 Oct 2020 19:46:39 |
| User entered empty; reason for change Data Entry Error | (b) (4), (b) (6) | 09 Oct 2020 22:36:28 |
| User entered '15' | (b) (4), (b) (6) | 09 Oct 2020 14:33:58 |

US3592229

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:21:23

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User entered 'breaths/min' | System | 15 Oct 2020 19:46:39 |
| User entered empty. | System | 09 Oct 2020 22:36:28 |
| User entered 'breaths/min' | System | 09 Oct 2020 14:33:58 |

US3592229

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:00:40 |
| User entered '134' reason for change: Data Entry Error | (b) (4) (b) (4), (b) (6) | 15 Oct 2020 19:46:39 |
| User entered empty; reason for change Data Entry Error | (b) (4), (b) (6) | 09 Oct 2020 22:36:28 |
| User entered '121' | (b) (4), (b) (6) | 09 Oct 2020 14:33:58 |

US3592229

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:21:23

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User entered 'mmHg' | System | 15 Oct 2020 19:46:39 |
| User entered empty. | System | 09 Oct 2020 22:36:28 |
| User entered 'mmHg' | System | 09 Oct 2020 14:33:58 |

US3592229

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:21:23

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:00:40 |
| User entered '87' reason for change: Data Entry Error | (b) (4) (b) (4), (b) (6) | 15 Oct 2020 19:46:39 |
| User entered empty; reason for change Data Entry Error | (b) (4), (b) (6) | 09 Oct 2020 22:36:28 |
| User entered '76' | (b) (4), (b) (6) | 09 Oct 2020 14:33:58 |

US3592229

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:21:23

Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User entered 'mmHg' | System | 15 Oct 2020 19:46:39 |
| User entered empty. | System | 09 Oct 2020 22:36:28 |
| User entered 'mmHg' | System | 09 Oct 2020 14:33:58 |

US3592229

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:21:23

[Height \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |

US3592229

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:21:23

Weight (derived)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |

US3592229

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:21:23

Was the physical examination performed?

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:00:40 |
| | (b) (4) | |
| User closed query 'Data is required. Please complete.' (Site from System). | System | 15 Oct 2020 19:45:20 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 15 Oct 2020 19:45:20 |
| User entered 'No (N)' reason for change: Data Entry Error | (b) (4), (b) (6) | 15 Oct 2020 19:45:20 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 15 Oct 2020 19:45:14 |
| User entered empty; reason for change Data Entry Error | (b) (4), (b) (6) | 15 Oct 2020 19:45:14 |
| User entered 'No (N)' | (b) (4), (b) (6) | 09 Oct 2020 14:34:08 |

US3592229

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:21:23

Date of examination (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:00:40 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 09 Oct 2020 14:34:08 |

US3592229

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:21:23

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:00:40 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 09 Oct 2020 14:34:35 |

US3592229

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:21:23

Collection date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User signature succeeded. | Terry Poling (b) (4) (b) (4) | 05 Mar 2021 16:00:40 |
| User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System). | System | 15 Oct 2020 19:45:45 |
| Query 'The Collection Date is not equal to Visit Date. System Please review and reconcile.' answered by data change (Site from System). | | 15 Oct 2020 19:45:45 |
| User entered '15 Oct 2020' reason for change: Data Entry Error | (b) (4), (b) (6) | 15 Oct 2020 19:45:45 |
| User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System). | System | 15 Oct 2020 19:45:08 |
| User entered '8 Oct 2020' | (b) (4), (b) (6) | 09 Oct 2020 14:34:35 |

US3592229

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:21:23

Collection time (00:00-23:59)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:00:40 |
| User entered '07:32' reason for change: Data Entry Error | (b) (4) (b) (4), (b) (6) | 15 Oct 2020 19:46:53 |
| User entered '07:22' reason for change: Data Entry Error | (b) (4), (b) (6) | 15 Oct 2020 19:45:45 |
| User entered '16:23' | (b) (4), (b) (6) | 09 Oct 2020 14:34:35 |

US3592229

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User entered '15 Oct 2020 07:32' | System | 15 Oct 2020 19:46:53 |
| User entered '15 Oct 2020 07:22' | System | 15 Oct 2020 19:45:45 |
| User entered '8 Oct 2020 16:23' | System | 09 Oct 2020 14:34:35 |

US3592229

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:21:23

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:00:40 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 09 Oct 2020 14:34:49 |

US3592229

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:21:23

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User entered 'I' | System | 09 Oct 2020 14:34:49 |

US3592229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| Data entry locked. | System | 18 Aug 2020 23:31:01 |
| User entered 'Day 64' | System | 18 Aug 2020 23:31:01 |

US3592229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-10-21T10:27:31', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '8b90a4f6-720e-44ef-8892-22399c6220c0' | System | 21 Oct 2020 15:27:46 |
| User entered 'No (N)' | System | 21 Oct 2020 15:27:46 |

US3592229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-10-21T10:27:40', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '8b90a4f6-720e-44ef-8892-22399c6220c0' | System | 21 Oct 2020 15:27:46 |
| User entered 'No (N)' | System | 21 Oct 2020 15:27:46 |

US3592229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-10-21T10:27:44', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '8b90a4f6-720e-44ef-8892-22399c6220c0' User entered '21 Oct 2020 10:27:44' | System | 21 Oct 2020 15:27:46 |
| | System | 21 Oct 2020 15:27:46 |

US3592229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| Data entry locked. | System | 18 Aug 2020 23:31:01 |
| User entered '18 Oct 2020 00:01' | System | 18 Aug 2020 23:31:01 |

US3592229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| Data entry locked. | System | 18 Aug 2020 23:31:01 |
| User entered '22 Oct 2020 23:59' | System | 18 Aug 2020 23:31:01 |

US3592229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| Data entry locked. | System | 18 Aug 2020 23:31:01 |
| User entered 'Day 71' | System | 18 Aug 2020 23:31:01 |

US3592229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-10-25T08:09:09', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: 'cbe7de31-bdfd-43e5-83ba-dc111f3763fd' | System | 25 Oct 2020 13:09:21 |
| User entered 'No (N)' | System | 25 Oct 2020 13:09:21 |

US3592229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-10-25T08:09:16', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: 'cbe7de31-bdfd-43e5-83ba-dc111f3763fd' | System | 25 Oct 2020 13:09:21 |
| User entered 'No (N)' | System | 25 Oct 2020 13:09:21 |

US3592229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-10-25T08:09:20', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: 'cbe7de31-bdfd-43e5-83ba-dc111f3763fd' User entered '25 Oct 2020 08:09:20' | System | 25 Oct 2020 13:09:21 |
| | System | 25 Oct 2020 13:09:21 |

US3592229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| Data entry locked. | System | 18 Aug 2020 23:31:01 |
| User entered '25 Oct 2020 00:01' | System | 18 Aug 2020 23:31:01 |

US3592229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| Data entry locked. | System | 18 Aug 2020 23:31:01 |
| User entered '29 Oct 2020 23:59' | System | 18 Aug 2020 23:31:01 |

US3592229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| Data entry locked. | System | 18 Aug 2020 23:31:01 |
| User entered 'Day 78' | System | 18 Aug 2020 23:31:01 |

US3592229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-11-01T17:55:51', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '810c52cc-f551-4760-ad98-56c06e28e471' | System | 01 Nov 2020 23:56:09 |
| User entered 'No (N)' | System | 01 Nov 2020 23:56:09 |

US3592229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-11-01T17:56:02', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '810c52cc-f551-4760-ad98-56c06e28e471' | System | 01 Nov 2020 23:56:09 |
| User entered 'No (N)' | System | 01 Nov 2020 23:56:09 |

US3592229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-11-01T17:56:06', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '810c52cc-f551-4760-ad98-56c06e28e471' User entered '01 Nov 2020 17:56:06' | System | 01 Nov 2020 23:56:09 |
| | System | 01 Nov 2020 23:56:09 |

US3592229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| Data entry locked. | System | 18 Aug 2020 23:31:01 |
| User entered '01 Nov 2020 00:01' | System | 18 Aug 2020 23:31:01 |

US3592229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| Data entry locked. | System | 18 Aug 2020 23:31:01 |
| User entered '05 Nov 2020 23:59' | System | 18 Aug 2020 23:31:01 |

US3592229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| Data entry locked. | System | 18 Aug 2020 23:31:01 |
| User entered 'Day 92' | System | 18 Aug 2020 23:31:01 |

US3592229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-11-17T12:38:32', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: 'a13c2fc8-c561-407f-95d2-9148ed8472e4' | System | 17 Nov 2020 18:38:42 |
| User entered 'No (N)' | System | 17 Nov 2020 18:38:42 |

US3592229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-11-17T12:38:36', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: 'a13c2fc8-c561-407f-95d2-9148ed8472e4' | System | 17 Nov 2020 18:38:42 |
| User entered 'No (N)' | System | 17 Nov 2020 18:38:42 |

US3592229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-11-17T12:38:39', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: 'a13c2fc8-c561-407f-95d2-9148ed8472e4' User entered '17 Nov 2020 12:38:39' | System | 17 Nov 2020 18:38:42 |
| | System | 17 Nov 2020 18:38:42 |

US3592229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| Data entry locked. | System | 18 Aug 2020 23:31:01 |
| User entered '15 Nov 2020 00:01' | System | 18 Aug 2020 23:31:01 |

US3592229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 10:47:50 |
| Data entry locked. | System | 18 Aug 2020 23:31:01 |
| User entered '19 Nov 2020 23:59' | System | 18 Aug 2020 23:31:01 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

TIMEPOINT

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered 'Day 96' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[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 (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-11-22T05:47:37', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '40efc1db-cb3f-42ea-929f-f5f042372c20' | System | 22 Nov 2020 11:47:48 |
| User entered 'No (N)' | System | 22 Nov 2020 11:47:48 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

Have you been exposed to someone with 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 (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-11-22T05:47:41', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '40efc1db-cb3f-42ea-929f-f5f042372c20' | System | 22 Nov 2020 11:47:48 |
| User entered 'No (N)' | System | 22 Nov 2020 11:47:48 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-11-22T05:47:44', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '40efc1db-cb3f-42ea-929f-f5f042372c20' User entered '22 Nov 2020 05:47:44' | System | 22 Nov 2020 11:47:48 |
| | System | 22 Nov 2020 11:47:48 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '19 Nov 2020 00:01' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '23 Nov 2020 23:59' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered 'Day 103' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[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 (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-11-26T13:38:15', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: 'ef867995-dbdb-4f34-aaea-d39c931783bd' User entered 'No (N)' | System | 26 Nov 2020 19:38:25 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

Have you been exposed to someone with 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 (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-11-26T13:38:19', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: 'ef867995-dbdb-4f34-aaea-d39c931783bd' User entered 'No (N)' | System | 26 Nov 2020 19:38:25 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-11-26T13:38:21', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: 'ef867995-dbdb-4f34-aaea-d39c931783bd' User entered '26 Nov 2020 13:38:21' | System | 26 Nov 2020 19:38:25 |
| | System | 26 Nov 2020 19:38:25 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '26 Nov 2020 00:01' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '30 Nov 2020 23:59' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered 'Day 110' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[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 (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-12-05T12:14:47', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: 'b32e4ca8-1ed1-49fc-b27b-0dbf41958c14' User entered 'No (N)' | System | 05 Dec 2020 18:14:59 |
| | System | 05 Dec 2020 18:14:59 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

Have you been exposed to someone with 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 (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-12-05T12:14:50', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: 'b32e4ca8-1ed1-49fc-b27b-0dbf41958c14' User entered 'No (N)' | System | 05 Dec 2020 18:14:59 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-12-05T12:14:57', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: 'b32e4ca8-1ed1-49fc-b27b-0dbf41958c14' User entered '05 Dec 2020 12:14:57' | System | 05 Dec 2020 18:14:59 |
| | System | 05 Dec 2020 18:14:59 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '03 Dec 2020 00:01' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '07 Dec 2020 23:59' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered 'Day 117' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[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 (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-12-12T21:42:20', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '22c757ea-b1a3-4bd1-b7b5-a48227f3826c' User entered 'No (N)' | System | 13 Dec 2020 03:42:33 |
| | System | 13 Dec 2020 03:42:33 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

Have you been exposed to someone with 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 (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-12-12T21:42:25', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '22c757ea-b1a3-4bd1-b7b5-a48227f3826c' User entered 'No (N)' | System | 13 Dec 2020 03:42:33 |
| | System | 13 Dec 2020 03:42:33 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-12-12T21:42:28', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '22c757ea-b1a3-4bd1-b7b5-a48227f3826c' User entered '12 Dec 2020 21:42:28' | System | 13 Dec 2020 03:42:33 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '10 Dec 2020 00:01' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '14 Dec 2020 23:59' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered 'Day 124' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[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 (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-12-17T05:21:19', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '4c1b086b-9a94-4786-a5d6-495cbe968fc6' User entered 'No (N)' | System | 17 Dec 2020 11:21:33 |
| | System | 17 Dec 2020 11:21:33 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

Have you been exposed to someone with 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 (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-12-17T05:21:28', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '4c1b086b-9a94-4786-a5d6-495cbe968fc6' User entered 'No (N)' | System | 17 Dec 2020 11:21:33 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-12-17T05:21:31', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '4c1b086b-9a94-4786-a5d6-495cbe968fc6' User entered '17 Dec 2020 05:21:31' | System | 17 Dec 2020 11:21:33 |
| | System | 17 Dec 2020 11:21:33 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '17 Dec 2020 00:01' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '21 Dec 2020 23:59' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered 'Day 131' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[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 (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-12-25T12:45:21', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: 'cd17792c-5cb9-44e0-95e3-89e0dabedd0a' User entered 'No (N)' | System | 25 Dec 2020 18:45:29 |
| | System | 25 Dec 2020 18:45:29 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

Have you been exposed to someone with 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 (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-12-25T12:45:23', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: 'cd17792c-5cb9-44e0-95e3-89e0dabedd0a' User entered 'No (N)' | System | 25 Dec 2020 18:45:29 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2020-12-25T12:45:26', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: 'cd17792c-5cb9-44e0-95e3-89e0dabedd0a' User entered '25 Dec 2020 12:45:26' | System | 25 Dec 2020 18:45:29 |
| | System | 25 Dec 2020 18:45:29 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '24 Dec 2020 00:01' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '28 Dec 2020 23:59' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered 'Day 138' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[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 (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2021-01-03T17:59:20', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '8fb11e2b-aa73-41d0-8d8c-bdc9c0aa6c4d' User entered 'No (N)' | System | 03 Jan 2021 23:59:32 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

Have you been exposed to someone with 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 (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2021-01-03T17:59:26', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '8fb11e2b-aa73-41d0-8d8c-bdc9c0aa6c4d' User entered 'No (N)' | System | 03 Jan 2021 23:59:32 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2021-01-03T17:59:28', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '8fb11e2b-aa73-41d0-8d8c-bdc9c0aa6c4d' User entered '03 Jan 2021 17:59:28' | System | 03 Jan 2021 23:59:32 |
| | System | 03 Jan 2021 23:59:32 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '31 Dec 2020 00:01' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '04 Jan 2021 23:59' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered 'Day 145' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[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 (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2021-01-08T17:28:24', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '80265ce4-308b-4d38-8bf9-31e0501586f2' User entered 'No (N)' | System | 08 Jan 2021 23:28:33 |
| | System | 08 Jan 2021 23:28:33 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

Have you been exposed to someone with 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 (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2021-01-08T17:28:26', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '80265ce4-308b-4d38-8bf9-31e0501586f2' User entered 'No (N)' | System | 08 Jan 2021 23:28:33 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2021-01-08T17:28:28', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '80265ce4-308b-4d38-8bf9-31e0501586f2' User entered '08 Jan 2021 17:28:28' | System | 08 Jan 2021 23:28:33 |
| | System | 08 Jan 2021 23:28:33 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '07 Jan 2021 00:01' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '11 Jan 2021 23:59' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered 'Day 152' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[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 (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2021-01-14T05:35:30', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: 'cc7457c5-a0fd-4b4c-b095-64fd98a8ba14' | System | 14 Jan 2021 11:35:44 |
| User entered 'No (N)' | System | 14 Jan 2021 11:35:44 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

Have you been exposed to someone with 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 (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2021-01-14T05:35:36', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: 'cc7457c5-a0fd-4b4c-b095-64fd98a8ba14' | System | 14 Jan 2021 11:35:44 |
| User entered 'No (N)' | System | 14 Jan 2021 11:35:44 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2021-01-14T05:35:40', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: 'cc7457c5-a0fd-4b4c-b095-64fd98a8ba14' User entered '14 Jan 2021 05:35:40' | System | 14 Jan 2021 11:35:44 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '14 Jan 2021 00:01' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '18 Jan 2021 23:59' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered 'Day 159' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[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 (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2021-01-22T18:31:09', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: 'ae29e150-462c-43c2-b081-4ca790e3ef72' | System | 23 Jan 2021 00:31:20 |
| User entered 'No (N)' | System | 23 Jan 2021 00:31:20 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

Have you been exposed to someone with 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 (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2021-01-22T18:31:14', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: 'ae29e150-462c-43c2-b081-4ca790e3ef72' | System | 23 Jan 2021 00:31:20 |
| User entered 'No (N)' | System | 23 Jan 2021 00:31:20 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2021-01-22T18:31:17', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: 'ae29e150-462c-43c2-b081-4ca790e3ef72' | System | 23 Jan 2021 00:31:20 |
| User entered '22 Jan 2021 18:31:17' | System | 23 Jan 2021 00:31:20 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '21 Jan 2021 00:01' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '25 Jan 2021 23:59' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered 'Day 166' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[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 (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2021-01-28T07:24:05', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '26373986-307b-43fe-974d-5109fe220ed5' User entered 'No (N)' | System | 28 Jan 2021 13:24:17 |
| | System | 28 Jan 2021 13:24:17 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

Have you been exposed to someone with 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 (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2021-01-28T07:24:08', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '26373986-307b-43fe-974d-5109fe220ed5' User entered 'No (N)' | System | 28 Jan 2021 13:24:17 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2021-01-28T07:24:11', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '26373986-307b-43fe-974d-5109fe220ed5' User entered '28 Jan 2021 07:24:11' | System | 28 Jan 2021 13:24:17 |
| | System | 28 Jan 2021 13:24:17 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '28 Jan 2021 00:01' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '01 Feb 2021 23:59' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered 'Day 173' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[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 (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2021-02-04T19:39:15', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: 'f1faadf9-52b2-4cfd-a19f-d5af2a81c8fd' User entered 'No (N)' | System | 05 Feb 2021 01:39:25 |
| | System | 05 Feb 2021 01:39:25 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

Have you been exposed to someone with 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 (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2021-02-04T19:39:19', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: 'f1faadf9-52b2-4cfd-a19f-d5af2a81c8fd' User entered 'No (N)' | System | 05 Feb 2021 01:39:25 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2021-02-04T19:39:22', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: 'f1faadf9-52b2-4cfd-a19f-d5af2a81c8fd' User entered '04 Feb 2021 19:39:22' | System | 05 Feb 2021 01:39:25 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '04 Feb 2021 00:01' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '08 Feb 2021 23:59' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered 'Day 180' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[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 (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2021-02-12T18:23:57', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '8442801b-c91d-46a6-a9cf-a76912033a43' User entered 'No (N)' | System | 13 Feb 2021 00:24:24 |
| | System | 13 Feb 2021 00:24:24 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

Have you been exposed to someone with 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 (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2021-02-12T18:24:03', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '8442801b-c91d-46a6-a9cf-a76912033a43' User entered 'No (N)' | System | 13 Feb 2021 00:24:24 |
| | System | 13 Feb 2021 00:24:24 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2021-02-12T18:24:06', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '8442801b-c91d-46a6-a9cf-a76912033a43' | System | 13 Feb 2021 00:24:24 |
| User entered '12 Feb 2021 18:24:06' | System | 13 Feb 2021 00:24:24 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '11 Feb 2021 00:01' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '15 Feb 2021 23:59' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered 'Day 187' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[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 (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2021-02-18T05:57:09', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '7546ac5f-893d-41cc-abb6-76fb3c2bb60e' | System | 18 Feb 2021 11:57:43 |
| User entered 'No (N)' | System | 18 Feb 2021 11:57:43 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

Have you been exposed to someone with 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 (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2021-02-18T05:57:15', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '7546ac5f-893d-41cc-abb6-76fb3c2bb60e' User entered 'Yes (Y)' | System | 18 Feb 2021 11:57:43 |
| | System | 18 Feb 2021 11:57:43 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Please 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 (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2021-02-18T05:57:26', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '7546ac5f-893d-41cc-abb6-76fb3c2bb60e' | System | 18 Feb 2021 11:57:43 |
| User entered 'I confirm I have read this message and will call the study clinic immediately (9)' | System | 18 Feb 2021 11:57:43 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2021-02-18T05:57:33', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '7546ac5f-893d-41cc-abbf-76fb3c2bb60e' User entered '18 Feb 2021 05:57:33' | System | 18 Feb 2021 11:57:43 |
| | System | 18 Feb 2021 11:57:43 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '18 Feb 2021 00:01' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '22 Feb 2021 23:59' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered 'Day 194' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[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 (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2021-02-27T17:00:44-06:00', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '696cc9c6-1de0-4a49-a904-5033f70dc91d' User entered 'No (N)' | System | 07 Mar 2021 00:13:33 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

Have you been exposed to someone with 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 (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2021-02-27T17:00:49-06:00', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '696cc9c6-1de0-4a49-a904-5033f70dc91d' User entered 'Yes (Y)' | System | 07 Mar 2021 00:13:33 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Please 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 (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2021-02-27T17:00:56-06:00', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '696cc9c6-1de0-4a49-a904-5033f70dc91d' | System | 07 Mar 2021 00:13:33 |
| User entered 'I confirm I have read this message and will call the study clinic immediately (9)' | System | 07 Mar 2021 00:13:33 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2021-02-27T17:00:59-06:00', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '696cc9c6-1de0-4a49-a904-5033f70dc91d' | System | 07 Mar 2021 00:13:33 |
| User entered '27 Feb 2021 23:00:59' | System | 07 Mar 2021 00:13:33 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '25 Feb 2021 00:01' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '01 Mar 2021 23:59' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered 'Day 201' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[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 (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2021-03-06T18:10:55-06:00', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: 'beffbd6a-685c-4261-8625-b3766610334b' User entered 'No (N)' | System | 07 Mar 2021 00:13:39 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

Have you been exposed to someone with 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 (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2021-03-06T18:11:02-06:00', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: 'beffbd6a-685c-4261-8625-b3766610334b' User entered 'No (N)' | System | 07 Mar 2021 00:13:39 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2021-03-06T18:11:05-06:00', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: 'beffbd6a-685c-4261-8625-b3766610334b' User entered '06 Mar 2021 18:11:05' | System | 07 Mar 2021 00:13:39 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '04 Mar 2021 00:01' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '08 Mar 2021 23:59' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered 'Day 208' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[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 (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2021-03-14T18:16:45-05:00', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: 'e3538305-764c-44d6-b0be-721869a75349' | System | 14 Mar 2021 23:16:57 |
| User entered 'No (N)' | System | 14 Mar 2021 23:16:57 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

Have you been exposed to someone with 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 (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2021-03-14T18:16:50-05:00', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: 'e3538305-764c-44d6-b0be-721869a75349' | System | 14 Mar 2021 23:16:57 |
| User entered 'No (N)' | System | 14 Mar 2021 23:16:57 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2021-03-14T18:16:54-05:00', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: 'e3538305-764c-44d6-b0be-721869a75349' | System | 14 Mar 2021 23:16:57 |
| User entered '14 Mar 2021 18:16:54' | System | 14 Mar 2021 23:16:57 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '11 Mar 2021 00:01' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '15 Mar 2021 23:59' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered 'Day 215' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[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 (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2021-03-19T11:21:53-05:00', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '1306b065-29c8-4af6-bfc0-e43ffc396c4a' User entered 'No (N)' | System | 19 Mar 2021 16:22:06 |
| | System | 19 Mar 2021 16:22:06 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

Have you been exposed to someone with 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 (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2021-03-19T11:21:57-05:00', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '1306b065-29c8-4af6-bfc0-e43ffc396c4a' | System | 19 Mar 2021 16:22:06 |
| User entered 'No (N)' | System | 19 Mar 2021 16:22:06 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2021-03-19T11:22:00-05:00', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '1306b065-29c8-4af6-bfc0-e43ffc396c4a' User entered '19 Mar 2021 11:22:00' | System | 19 Mar 2021 16:22:06 |
| | System | 19 Mar 2021 16:22:06 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '18 Mar 2021 00:01' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '22 Mar 2021 23:59' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered 'Day 222' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[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 (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2021-03-29T14:23:53-05:00', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: 'ac74519f-5ce9-45d1-8f45-0b7a48539f18' | System | 29 Mar 2021 19:24:07 |
| User entered 'No (N)' | System | 29 Mar 2021 19:24:07 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

Have you been exposed to someone with 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 (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2021-03-29T14:23:56-05:00', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: 'ac74519f-5ce9-45d1-8f45-0b7a48539f18' | System | 29 Mar 2021 19:24:07 |
| User entered 'No (N)' | System | 29 Mar 2021 19:24:07 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2021-03-29T14:23:58-05:00', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: 'ac74519f-5ce9-45d1-8f45-0b7a48539f18' | System | 29 Mar 2021 19:24:07 |
| User entered '29 Mar 2021 14:23:58' | System | 29 Mar 2021 19:24:07 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '25 Mar 2021 00:01' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '29 Mar 2021 23:59' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered 'Day 229' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[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 (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2021-04-01T10:32:40-05:00', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: 'c56e3949-4a5e-4faf-88a5-811d56636c40' | System | 01 Apr 2021 15:32:47 |
| User entered 'No (N)' | System | 01 Apr 2021 15:32:47 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

Have you been exposed to someone with 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 (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2021-04-01T10:32:42-05:00', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: 'c56e3949-4a5e-4faf-88a5-811d56636c40' | System | 01 Apr 2021 15:32:47 |
| User entered 'No (N)' | System | 01 Apr 2021 15:32:47 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2021-04-01T10:32:45-05:00', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: 'c56e3949-4a5e-4faf-88a5-811d56636c40' | System | 01 Apr 2021 15:32:47 |
| User entered '01 Apr 2021 10:32:45' | System | 01 Apr 2021 15:32:47 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '01 Apr 2021 00:01' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '05 Apr 2021 23:59' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered 'Day 236' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[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 (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2021-04-11T20:38:47-05:00', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '81ed6fbe-bb5d-4029-9132-0ceefab4a5f' User entered 'No (N)' | System | 12 Apr 2021 01:38:59 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

Have you been exposed to someone with 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 (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2021-04-11T20:38:50-05:00', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '81ed6fbe-bb5d-4029-9132-0ceefab4a5f' User entered 'No (N)' | System | 12 Apr 2021 01:38:59 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2021-04-11T20:38:53-05:00', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '81ed6fbe-bb5d-4029-9132-0ceefab4a5f' User entered '11 Apr 2021 20:38:53' | System | 12 Apr 2021 01:38:59 |
| | System | 12 Apr 2021 01:38:59 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '08 Apr 2021 00:01' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '12 Apr 2021 23:59' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered 'Day 243' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[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 (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2021-04-15T17:39:49-05:00', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '0974a9c5-2ee8-4dc2-ade4-307f54864d7a' User entered 'No (N)' | System | 15 Apr 2021 22:40:02 |
| | System | 15 Apr 2021 22:40:02 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

Have you been exposed to someone with 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 (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2021-04-15T17:39:54-05:00', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '0974a9c5-2ee8-4dc2-ade4-307f54864d7a' User entered 'No (N)' | System | 15 Apr 2021 22:40:02 |
| | System | 15 Apr 2021 22:40:02 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2021-04-15T17:39:57-05:00', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '0974a9c5-2ee8-4dc2-ade4-307f54864d7a' User entered '15 Apr 2021 17:39:57' | System | 15 Apr 2021 22:40:02 |
| | System | 15 Apr 2021 22:40:02 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '15 Apr 2021 00:01' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '19 Apr 2021 23:59' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered 'Day 250' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[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 (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2021-04-22T18:20:21-05:00', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '34b56c09-4401-486e-aac0-99611cf5a08e' User entered 'No (N)' | System | 22 Apr 2021 23:20:32 |
| | System | 22 Apr 2021 23:20:32 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

Have you been exposed to someone with 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 (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2021-04-22T18:20:25-05:00', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '34b56c09-4401-486e-aac0-99611cf5a08e' User entered 'No (N)' | System | 22 Apr 2021 23:20:32 |
| | System | 22 Apr 2021 23:20:32 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2021-04-22T18:20:28-05:00', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '34b56c09-4401-486e-aac0-99611cf5a08e' User entered '22 Apr 2021 18:20:28' | System | 22 Apr 2021 23:20:32 |
| | System | 22 Apr 2021 23:20:32 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '22 Apr 2021 00:01' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '26 Apr 2021 23:59' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered 'Day 257' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[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 (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2021-04-30T20:46:29-05:00', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '1102ea6a-123c-44fb-b533-f4e0d593ffd0' | System | 01 May 2021 01:46:38 |
| User entered 'No (N)' | System | 01 May 2021 01:46:38 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

Have you been exposed to someone with 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 (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2021-04-30T20:46:32-05:00', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '1102ea6a-123c-44fb-b533-f4e0d593ffd0' | System | 01 May 2021 01:46:38 |
| User entered 'No (N)' | System | 01 May 2021 01:46:38 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2021-04-30T20:46:35-05:00', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: '1102ea6a-123c-44fb-b533-f4e0d593ffd0' | System | 01 May 2021 01:46:38 |
| User entered '30 Apr 2021 20:46:35' | System | 01 May 2021 01:46:38 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '29 Apr 2021 00:01' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '03 May 2021 23:59' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered 'Day 264' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '06 May 2021 00:01' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '10 May 2021 23:59' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered 'Day 271' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '13 May 2021 00:01' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '17 May 2021 23:59' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered 'Day 278' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '20 May 2021 00:01' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '24 May 2021 23:59' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered 'Day 285' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '27 May 2021 00:01' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '31 May 2021 23:59' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered 'Day 292' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '03 Jun 2021 00:01' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '07 Jun 2021 23:59' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered 'Day 299' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '10 Jun 2021 00:01' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '14 Jun 2021 23:59' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered 'Day 306' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '17 Jun 2021 00:01' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '21 Jun 2021 23:59' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered 'Day 313' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '24 Jun 2021 00:01' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '28 Jun 2021 23:59' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered 'Day 320' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '01 Jul 2021 00:01' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '05 Jul 2021 23:59' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered 'Day 327' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '08 Jul 2021 00:01' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '12 Jul 2021 23:59' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered 'Day 334' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '15 Jul 2021 00:01' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '19 Jul 2021 23:59' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered 'Day 341' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '22 Jul 2021 00:01' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '26 Jul 2021 23:59' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered 'Day 348' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '29 Jul 2021 00:01' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '02 Aug 2021 23:59' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered 'Day 355' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '05 Aug 2021 00:01' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '09 Aug 2021 23:59' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered 'Day 362' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '12 Aug 2021 00:01' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '16 Aug 2021 23:59' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered 'Day 369' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '19 Aug 2021 00:01' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '23 Aug 2021 23:59' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered 'Day 376' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '26 Aug 2021 00:01' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '30 Aug 2021 23:59' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered 'Day 383' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '02 Sep 2021 00:01' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '06 Sep 2021 23:59' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered 'Day 390' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '09 Sep 2021 00:01' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '13 Sep 2021 23:59' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered 'Day 397' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '16 Sep 2021 00:01' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '20 Sep 2021 23:59' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered 'Day 404' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '23 Sep 2021 00:01' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '27 Sep 2021 23:59' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered 'Day 411' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '30 Sep 2021 00:01' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '04 Oct 2021 23:59' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered 'Day 418' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '07 Oct 2021 00:01' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '11 Oct 2021 23:59' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered 'Day 425' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '14 Oct 2021 00:01' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '18 Oct 2021 23:59' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered 'Day 432' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '21 Oct 2021 00:01' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '25 Oct 2021 23:59' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered 'Day 439' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '28 Oct 2021 00:01' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '01 Nov 2021 23:59' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered 'Day 446' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '04 Nov 2021 00:01' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '08 Nov 2021 23:59' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered 'Day 453' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '11 Nov 2021 00:01' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '15 Nov 2021 23:59' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered 'Day 460' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '18 Nov 2021 00:01' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '22 Nov 2021 23:59' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered 'Day 467' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '25 Nov 2021 00:01' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '29 Nov 2021 23:59' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered 'Day 474' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '02 Dec 2021 00:01' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '06 Dec 2021 23:59' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered 'Day 481' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '09 Dec 2021 00:01' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '13 Dec 2021 23:59' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered 'Day 488' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '16 Dec 2021 00:01' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '20 Dec 2021 23:59' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered 'Day 495' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '23 Dec 2021 00:01' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '27 Dec 2021 23:59' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered 'Day 502' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '30 Dec 2021 00:01' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '03 Jan 2022 23:59' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered 'Day 509' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '06 Jan 2022 00:01' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '10 Jan 2022 23:59' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered 'Day 516' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '13 Jan 2022 00:01' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '17 Jan 2022 23:59' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered 'Day 523' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '20 Jan 2022 00:01' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '24 Jan 2022 23:59' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered 'Day 530' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '27 Jan 2022 00:01' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '31 Jan 2022 23:59' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered 'Day 537' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '03 Feb 2022 00:01' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '07 Feb 2022 23:59' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered 'Day 544' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '10 Feb 2022 00:01' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '14 Feb 2022 23:59' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered 'Day 551' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '17 Feb 2022 00:01' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '21 Feb 2022 23:59' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered 'Day 558' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '24 Feb 2022 00:01' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '28 Feb 2022 23:59' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered 'Day 565' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '03 Mar 2022 00:01' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '07 Mar 2022 23:59' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered 'Day 572' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '10 Mar 2022 00:01' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '14 Mar 2022 23:59' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered 'Day 579' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '17 Mar 2022 00:01' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '21 Mar 2022 23:59' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered 'Day 586' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '24 Mar 2022 00:01' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '28 Mar 2022 23:59' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered 'Day 593' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '31 Mar 2022 00:01' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '04 Apr 2022 23:59' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered 'Day 600' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '07 Apr 2022 00:01' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '11 Apr 2022 23:59' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered 'Day 607' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '14 Apr 2022 00:01' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '18 Apr 2022 23:59' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered 'Day 614' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '21 Apr 2022 00:01' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '25 Apr 2022 23:59' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered 'Day 621' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '28 Apr 2022 00:01' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '02 May 2022 23:59' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered 'Day 628' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '05 May 2022 00:01' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '09 May 2022 23:59' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered 'Day 635' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '12 May 2022 00:01' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '16 May 2022 23:59' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered 'Day 642' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '19 May 2022 00:01' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '23 May 2022 23:59' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered 'Day 649' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '26 May 2022 00:01' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '30 May 2022 23:59' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered 'Day 656' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '02 Jun 2022 00:01' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '06 Jun 2022 23:59' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered 'Day 663' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '09 Jun 2022 00:01' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '13 Jun 2022 23:59' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered 'Day 670' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '16 Jun 2022 00:01' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '20 Jun 2022 23:59' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered 'Day 677' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '23 Jun 2022 00:01' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '27 Jun 2022 23:59' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered 'Day 684' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '30 Jun 2022 00:01' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '04 Jul 2022 23:59' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered 'Day 691' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '07 Jul 2022 00:01' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '11 Jul 2022 23:59' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered 'Day 698' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '14 Jul 2022 00:01' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '18 Jul 2022 23:59' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered 'Day 705' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '21 Jul 2022 00:01' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '25 Jul 2022 23:59' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered 'Day 712' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '28 Jul 2022 00:01' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '01 Aug 2022 23:59' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered 'Day 719' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '04 Aug 2022 00:01' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '08 Aug 2022 23:59' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered 'Day 726' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '11 Aug 2022 00:01' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '15 Aug 2022 23:59' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered 'Day 733' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '18 Aug 2022 00:01' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '22 Aug 2022 23:59' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered 'Day 740' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '25 Aug 2022 00:01' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '29 Aug 2022 23:59' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered 'Day 747' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '01 Sep 2022 00:01' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '05 Sep 2022 23:59' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered 'Day 754' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '08 Sep 2022 00:01' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '12 Sep 2022 23:59' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered 'Day 761' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '15 Sep 2022 00:01' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '19 Sep 2022 23:59' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered 'Day 768' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '22 Sep 2022 00:01' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '26 Sep 2022 23:59' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered 'Day 775' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '29 Sep 2022 00:01' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '03 Oct 2022 23:59' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered 'Day 782' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '06 Oct 2022 00:01' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '10 Oct 2022 23:59' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered 'Day 789' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '13 Oct 2022 00:01' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '17 Oct 2022 23:59' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered 'Day 796' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '20 Oct 2022 00:01' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:21:23

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 22:39:36 |
| Amendment Manager: User entered '24 Oct 2022 23:59' | System | 19 Nov 2020 22:39:36 |

US3592229

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 08:21:23

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 20:27:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2021-02-27T17:00:10-06:00', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: 'e68705bc-32bf-4a7a-8ac5-51ead18dab82' | System | 27 Feb 2021 23:00:18 |
| User entered 'No (N)' | System | 27 Feb 2021 23:00:18 |

US3592229

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 08:21:23

[Date & Time of Submission](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 20:27:37 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (96F8E3E5-DB94-415E-9F4A-CA8FD74F05BC)', Time: '2021-02-27T17:00:15-06:00', User OID: 'PatientReportedOutcome (US3592229)', ODM File OID: 'e68705bc-32bf-4a7a-8ac5-51ead18dab82' | System | 27 Feb 2021 23:00:18 |
| User entered '27 Feb 2021 23:00:15' | System | 27 Feb 2021 23:00:18 |

US3592229

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:21:23

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:55:09 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 15:44:20 |

US3592229

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:21:23

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:55:09 |
| User entered '9 Nov 2020' | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 15:44:20 |

US3592229

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:21:23

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:55:09 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 15:44:20 |

US3592229

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:21:23

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:55:09 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 15:44:20 |

US3592229

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:21:23

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User signature succeeded. | Terry Poling (b) (4) | 05 Mar 2021 16:55:09 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 15:44:30 |

US3592229

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:21:23

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Mar 2021 10:26:11 |
| User entered 'l' | System | 11 Nov 2020 15:44:30 |

US3592229

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:21:23

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 20:11:00 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:37:55 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 16 Dec 2020 18:02:47 |

US3592229

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:21:23

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 20:11:00 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:37:55 |
| User entered '15 Dec 2020' | (b) (4) (b) (4), (b) (6) | 16 Dec 2020 18:02:47 |

US3592229

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:21:23

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 20:11:00 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:37:55 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4) (b) (4), (b) (6) | 16 Dec 2020 18:02:47 |

US3592229

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:21:23

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 20:11:00 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:37:55 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 16 Dec 2020 18:02:47 |

US3592229

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:21:23

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 20:11:00 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:37:55 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 16 Dec 2020 18:02:52 |

US3592229

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:21:23

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 20:11:00 |
| User entered 'l' | System | 16 Dec 2020 18:02:52 |

US3592229

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:21:23

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 20:11:00 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:37:55 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 13 Jan 2021 19:40:24 |

US3592229

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:21:23

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 20:11:00 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:37:55 |
| User entered '12 Jan 2021' | (b) (4) (b) (4), (b) (6) | 13 Jan 2021 19:40:24 |

US3592229

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:21:23

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 20:11:00 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:37:55 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4) (b) (4), (b) (6) | 13 Jan 2021 19:40:24 |

US3592229

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:21:23

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 20:11:00 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:37:55 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 13 Jan 2021 19:40:24 |

US3592229

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:21:23

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 20:11:00 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:37:55 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 13 Jan 2021 19:40:35 |

US3592229

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:21:23

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 20:11:00 |
| User entered 'l' | System | 13 Jan 2021 19:40:35 |

US3592229

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:21:23

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 20:11:01 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:37:55 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 01 Mar 2021 17:13:00 |

US3592229

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:21:23

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 20:11:01 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:37:55 |
| User entered '12 Feb 2021' | (b) (4) (b) (4), (b) (6) | 01 Mar 2021 17:13:00 |

US3592229

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:21:23

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 20:11:01 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:37:55 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4) (b) (4), (b) (6) | 01 Mar 2021 17:13:00 |

US3592229

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:21:23

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 20:11:01 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:37:55 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 01 Mar 2021 17:13:00 |

US3592229

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:21:23

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 20:11:01 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:37:55 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 01 Mar 2021 17:13:06 |

US3592229

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:21:23

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 20:11:01 |
| User entered 'l' | System | 01 Mar 2021 17:13:06 |

US3592229

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:21:23

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 20:09:15 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:37:55 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 07 Apr 2021 16:17:51 |

US3592229

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 20:09:15 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:37:55 |
| User entered '19 Mar 2021' | (b) (4) (b) (4), (b) (6) | 07 Apr 2021 16:17:51 |

US3592229

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|--------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 20:09:15 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:37:55 |
| User entered 'Clinic (Clinic)' | (b) (4) (b) (4), (b) (6) | 07 Apr 2021 16:17:51 |

US3592229

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:21:23

[Folder OID](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 20:09:15 |
| User entered 'VISIT4' | System | 07 Apr 2021 16:17:51 |

US3592229

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:21:23

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 20:09:15 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:37:55 |
| User closed query 'Per CDM: Visit 4 Day 209 and OL-Day57are both dated 19Mar2021. However, the data on the Vital Sign forms in these two visits do not match. If confirmed the visits occurred on the same day, the data must match. Please review and reconcile.' (Site from DM). | (b) (4) (b) (4), (b) (6) | 14 Apr 2021 06:33:19 |
| Query 'Per CDM: Visit 4 Day 209 and OL-Day57are both dated 19Mar2021. However, the data on the Vital Sign forms in these two visits do not match. If confirmed the visits occurred on the same day, the data must match. Please review and reconcile.' | (b) (4), (b) (6) | 12 Apr 2021 22:11:54 |
| answered with 'page updated ' (Site from DM). User entered 'Yes (Y)' reason for change: Data Entry Error | (b) (4), (b) (6) | 12 Apr 2021 22:11:47 |
| User opened query 'Per CDM: Visit 4 Day 209 and OL-Day57are both dated 19Mar2021. However, the data on the Vital Sign forms in these two visits do not match. If confirmed the visits occurred on the same day, the data must match. Please review and reconcile.' (Site from DM). | (b) (4), (b) (6) | 12 Apr 2021 06:25:27 |
| User entered 'No (N)' | (b) (4), (b) (6) | 07 Apr 2021 16:18:06 |

US3592229

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:21:23

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 20:09:15 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:37:55 |
| User entered '19 Mar 2021' reason for change: Data Entry Error | (b) (4), (b) (6) | 12 Apr 2021 22:11:47 |
| User entered empty. | (b) (4), (b) (6) | 07 Apr 2021 16:18:06 |

US3592229

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 20:09:15 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:37:55 |
| User entered '11:07' reason for change: Data Entry Error | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 22:11:47 |
| User entered empty. | (b) (4), (b) (6) | 07 Apr 2021 16:18:06 |

US3592229

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 20:09:15 |
| User entered '19 Mar 2021 11:07' | System | 12 Apr 2021 22:11:47 |
| User entered empty. | System | 07 Apr 2021 16:18:06 |

US3592229

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:21:23

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 20:09:15 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:37:55 |
| User entered '36.9' C reason for change: Data Entry Error | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 22:11:47 |
| User entered empty. | (b) (4), (b) (6) | 07 Apr 2021 16:18:06 |

US3592229

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:21:23

[Route of measurement](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 20:09:15 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:37:55 |
| User entered 'Oral (Oral)' reason for change: Data Entry Error | (b) (4), (b) (6) | 12 Apr 2021 22:11:47 |
| User entered empty. | (b) (4), (b) (6) | 07 Apr 2021 16:18:06 |

US3592229

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:21:23

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 20:09:15 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:37:55 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 07 Apr 2021 16:18:06 |

US3592229

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:21:23

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 20:09:15 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:37:55 |
| User entered '62' reason for change: Data Entry Error | (b) (4), (b) (6) | 12 Apr 2021 22:11:47 |
| User entered empty. | (b) (4), (b) (6) | 07 Apr 2021 16:18:06 |

US3592229

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:21:23

[Pulse units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 20:09:15 |
| User entered 'bpm' | System | 12 Apr 2021 22:11:47 |
| User entered empty. | System | 07 Apr 2021 16:18:06 |

US3592229

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|---|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 20:09:15 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:37:55 |
| User entered '16' reason for change: Data Entry Error | (b) (4), (b) (6) | 12 Apr 2021 22:11:47 |
| User entered empty. | (b) (4), (b) (6) | 07 Apr 2021 16:18:06 |

US3592229

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:21:23

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 20:09:15 |
| User entered 'breaths/min' | System | 12 Apr 2021 22:11:47 |
| User entered empty. | System | 07 Apr 2021 16:18:06 |

US3592229

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 20:09:15 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:37:55 |
| User entered '159' reason for change: Data Entry Error | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 22:11:47 |
| User entered empty. | (b) (4), (b) (6) | 07 Apr 2021 16:18:06 |

US3592229

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:21:23

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 20:09:15 |
| User entered 'mmHg' | System | 12 Apr 2021 22:11:47 |
| User entered empty. | System | 07 Apr 2021 16:18:06 |

US3592229

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|---|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 20:09:15 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:37:55 |
| User entered '88' reason for change: Data Entry Error | (b) (4), (b) (6) | 12 Apr 2021 22:11:47 |
| User entered empty. | (b) (4), (b) (6) | 07 Apr 2021 16:18:06 |

US3592229

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:21:23

Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 20:09:15 |
| User entered 'mmHg' | System | 12 Apr 2021 22:11:47 |
| User entered empty. | System | 07 Apr 2021 16:18:06 |

US3592229

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:21:23

[Height \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 20:09:15 |

US3592229

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:21:23

Weight (derived)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 20:09:15 |

US3592229

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:21:23

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 20:09:15 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:37:55 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 07 Apr 2021 16:18:12 |

US3592229

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:21:23

Date of examination (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 20:09:15 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:37:55 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 07 Apr 2021 16:18:12 |

US3592229

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:21:23

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 20:09:15 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:37:55 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 07 Apr 2021 16:18:37 |

US3592229

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:21:23

Collection date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 20:09:15 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:37:55 |
| User entered '19 Mar 2021' | (b) (4) (b) (4), (b) (6) | 07 Apr 2021 16:18:37 |

US3592229

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:21:23

Collection time (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 20:09:15 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:37:55 |
| User entered '11:38' | (b) (4) (b) (4), (b) (6) | 07 Apr 2021 16:18:37 |

US3592229

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 20:09:15 |
| User entered '19 Mar 2021 11:38' | System | 07 Apr 2021 16:18:37 |

US3592229

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:21:23

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 20:09:15 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:37:55 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 07 Apr 2021 16:18:42 |

US3592229

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:21:23

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 20:09:15 |
| User entered 'I' | System | 07 Apr 2021 16:18:42 |

US3592229

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:21:23

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:37:55 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 21 Apr 2021 13:29:24 |

US3592229

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:21:23

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:37:55 |
| User entered '14 Apr 2021' | (b) (4) (b) (4), (b) (6) | 21 Apr 2021 13:29:24 |

US3592229

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:21:23

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:37:55 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4) (b) (4), (b) (6) | 21 Apr 2021 13:29:24 |

US3592229

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:21:23

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:37:55 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 21 Apr 2021 13:29:24 |

US3592229

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:21:23

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:37:55 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 21 Apr 2021 13:29:29 |

US3592229

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:21:23

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'l' | System | 21 Apr 2021 13:29:29 |

US3592229

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

Form: Visit Date

Generated On: 10 Jun 2021 08:21:23

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 09:45:13 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:37:55 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 28 Jan 2021 21:29:31 |

US3592229

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

Form: Visit Date

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 09:45:13 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:37:55 |
| User entered '25 Jan 2021' | (b) (4) (b) (4), (b) (6) | 28 Jan 2021 21:29:31 |

US3592229

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

Form: Visit Date

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|--------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 09:45:13 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:37:55 |
| User entered 'Clinic (Clinic)' | (b) (4) (b) (4), (b) (6) | 28 Jan 2021 21:29:31 |

US3592229

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

Form: Visit Date

Generated On: 10 Jun 2021 08:21:23

[Folder OID](#)

| Audit | User | Time (GMT) |
|------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 09:45:13 |
| User entered 'UNBLND_DECIDE' | System | 28 Jan 2021 21:29:31 |

US3592229

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

Form: Unblinding

Generated On: 10 Jun 2021 08:21:23

Date of updated informed consent (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 09:45:13 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:37:55 |
| User entered '25 Jan 2021' | (b) (4) (b) (4), (b) (6) | 28 Jan 2021 21:30:04 |

US3592229

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

Form: Unblinding

Generated On: 10 Jun 2021 08:21:23

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 09:45:13 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:37:55 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 09 Apr 2021 14:09:30 |
| Amendment Manager inserted this DataPoint. | System | 06 Mar 2021 05:42:02 |

US3592229

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

Form: Unblinding

Generated On: 10 Jun 2021 08:21:23

[Was the participant unblinded?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 09:45:13 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:37:55 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 28 Jan 2021 21:30:04 |

US3592229

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

Form: Unblinding

Generated On: 10 Jun 2021 08:21:23

[Under what version of the Protocol was the Participant unblinded?](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 09:45:13 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:37:55 |
| User closed query 'Per IRT: system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM). | (b) (4) (b) (4), (b) (6) | 12 Apr 2021 06:37:04 |
| Query 'Per IRT: system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' answered with 'updated ' (Site from DM). | (b) (4), (b) (6) | 09 Apr 2021 14:09:34 |
| User entered 'Amendment 6 or later (Amendment 6 or later)' | (b) (4), (b) (6) | 09 Apr 2021 14:09:30 |
| 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) | 09 Apr 2021 04:12:57 |
| Amendment Manager inserted this DataPoint. | System | 06 Mar 2021 05:42:02 |

US3592229

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

Form: Unblinding

Generated On: 10 Jun 2021 08:21:23

Date of unblinding (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 09:45:13 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:37:55 |
| User entered '25 Jan 2021' | (b) (4) (b) (4), (b) (6) | 28 Jan 2021 21:30:04 |

US3592229

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

Form: Unblinding

Generated On: 10 Jun 2021 08:21:23

[Participant randomization assignment](#)

| Audit | User | Time (GMT) |
|----------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 09:45:13 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:37:55 |
| User entered 'Placebo (Placebo)' | (b) (4) (b) (4), (b) (6) | 28 Jan 2021 21:30:04 |

US3592229

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

Form: Unblinding

Generated On: 10 Jun 2021 08:21:23

[Actual Dose 1](#)

| Audit | User | Time (GMT) |
|----------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 09:45:13 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:37:55 |
| User entered 'Placebo (Placebo)' | (b) (4) (b) (4), (b) (6) | 28 Jan 2021 21:30:04 |

US3592229

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

Form: Unblinding

Generated On: 10 Jun 2021 08:21:23

[Actual Dose 2](#)

| Audit | User | Time (GMT) |
|----------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 09:45:13 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:37:55 |
| User entered 'Placebo (Placebo)' | (b) (4) (b) (4), (b) (6) | 28 Jan 2021 21:30:04 |

US3592229

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

Form: Unblinding

Generated On: 10 Jun 2021 08:21:23

[Will participant receive mRNA-1273?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 09:45:13 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:37:55 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 28 Jan 2021 21:30:04 |

US3592229

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

Form: Unblinding

Generated On: 10 Jun 2021 08:21:23

[Placebo Only Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 09:45:13 |
| User entered 'I' | System | 28 Jan 2021 21:30:04 |

US3592229

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

Form: Unblinding

Generated On: 10 Jun 2021 08:21:23

[Continuing with mRNA-1273](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 09:45:13 |
| User entered 'I' | System | 28 Jan 2021 21:30:04 |

US3592229

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:21:23

Height

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 09:45:13 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:37:55 |
| User entered '169.0' cm | (b) (4) (b) (4), (b) (6) | 28 Jan 2021 21:32:32 |

US3592229

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:21:23

[Weight](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 09:45:13 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:37:55 |
| User entered '101.8' kg | (b) (4) (b) (4), (b) (6) | 28 Jan 2021 21:32:32 |

US3592229

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:21:23

BMI (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 09:45:13 |
| User entered '35.64301' | System | 28 Jan 2021 21:32:32 |
| DataPoint set to visible. | System | 28 Jan 2021 21:30:04 |

US3592229

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:21:23

Height

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 09:45:13 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:37:55 |
| User entered '169.0' cm | (b) (4) (b) (4), (b) (6) | 28 Jan 2021 21:32:32 |

US3592229

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:21:23

[Weight](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 09:45:13 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:37:55 |
| User entered '101.8' kg | (b) (4) (b) (4), (b) (6) | 28 Jan 2021 21:32:32 |

US3592229

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:21:23

BMI (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 09:45:13 |
| User entered '35.64301' | System | 28 Jan 2021 21:32:32 |
| DataPoint set to visible. | System | 28 Jan 2021 21:30:04 |

US3592229

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:21:23

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 09:45:13 |
| User accepted default value 'Pre-Dose (PREDOSE)' | | 28 Jan 2021 21:32:32 |

US3592229

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:21:23

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 09:45:13 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:37:55 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 28 Jan 2021 21:32:32 |

US3592229

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:21:23

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 09:45:13 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:37:55 |
| User entered '25 Jan 2021' | (b) (4) (b) (4), (b) (6) | 28 Jan 2021 21:32:32 |

US3592229

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 09:45:13 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:37:55 |
| User entered '10:27' | (b) (4) (b) (4), (b) (6) | 28 Jan 2021 21:32:32 |

US3592229

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 09:45:13 |
| User entered '25 Jan 2021 10:27' | System | 28 Jan 2021 21:32:32 |

US3592229

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:21:23

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 09:45:13 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:37:55 |
| User entered '36.8' C | (b) (4) (b) (4), (b) (6) | 28 Jan 2021 21:32:32 |

US3592229

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:21:23

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 09:45:13 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:37:55 |
| User entered 'Oral (Oral)' | (b) (4) (b) (4), (b) (6) | 28 Jan 2021 21:32:32 |

US3592229

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:21:23

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 09:45:13 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:37:55 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 28 Jan 2021 21:32:32 |

US3592229

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:21:23

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 09:45:13 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:37:55 |
| User entered '100' | (b) (4) (b) (4), (b) (6) | 28 Jan 2021 21:32:32 |

US3592229

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:21:23

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 09:45:13 |
| User entered 'bpm' | System | 28 Jan 2021 21:32:32 |

US3592229

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 09:45:13 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:37:55 |
| User entered '16' | (b) (4) (b) (4), (b) (6) | 28 Jan 2021 21:32:32 |

US3592229

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:21:23

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 09:45:13 |
| User entered 'breaths/min' | System | 28 Jan 2021 21:32:32 |

US3592229

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:21:23

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 09:45:13 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:37:55 |
| User entered '142' | (b) (4) (b) (4), (b) (6) | 28 Jan 2021 21:32:32 |

US3592229

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:21:23

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 09:45:13 |
| User entered 'mmHg' | System | 28 Jan 2021 21:32:32 |

US3592229

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 09:45:13 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:37:55 |
| User entered '101' | (b) (4) (b) (4), (b) (6) | 28 Jan 2021 21:32:32 |

US3592229

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:21:23

Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 09:45:13 |
| User entered 'mmHg' | System | 28 Jan 2021 21:32:32 |

US3592229

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:21:23

Height

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 09:45:13 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:37:55 |
| User entered '169.0' cm | (b) (4) (b) (4), (b) (6) | 28 Jan 2021 21:32:32 |

US3592229

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:21:23

[Weight](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 09:45:13 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:37:55 |
| User entered '101.8' kg | (b) (4) (b) (4), (b) (6) | 28 Jan 2021 21:32:32 |

US3592229

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:21:23

BMI (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 09:45:13 |
| User entered '35.64301' | System | 28 Jan 2021 21:32:32 |
| DataPoint set to visible. | System | 28 Jan 2021 21:30:04 |

US3592229

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:21:23

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 09:45:13 |
| User accepted default value 'Post-Dose (POSTDOSE)' | | 28 Jan 2021 21:32:32 |

US3592229

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:21:23

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 09:45:13 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:37:55 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 28 Jan 2021 21:32:32 |

US3592229

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:21:23

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 09:45:13 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:37:55 |
| User entered '25 Jan 2021' | (b) (4) (b) (4), (b) (6) | 28 Jan 2021 21:32:32 |

US3592229

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 09:45:13 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:37:55 |
| User entered '11:20' | (b) (4) (b) (4), (b) (6) | 28 Jan 2021 21:32:32 |

US3592229

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 09:45:13 |
| User entered '25 Jan 2021 11:20' | System | 28 Jan 2021 21:32:32 |

US3592229

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:21:23

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 09:45:13 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:37:55 |
| User entered '98.5' F | (b) (4) (b) (4), (b) (6) | 28 Jan 2021 21:32:32 |

US3592229

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:21:23

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 09:45:13 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:37:55 |
| User entered 'Oral (Oral)' | (b) (4) (b) (4), (b) (6) | 28 Jan 2021 21:32:32 |

US3592229

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:21:23

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 09:45:13 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:37:55 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 28 Jan 2021 21:32:32 |

US3592229

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:21:23

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 09:45:13 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:37:55 |
| User entered '95' | (b) (4) (b) (4), (b) (6) | 28 Jan 2021 21:32:32 |

US3592229

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:21:23

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 09:45:13 |
| User entered 'bpm' | System | 28 Jan 2021 21:32:32 |

US3592229

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 09:45:13 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:37:55 |
| User entered '16' | (b) (4) (b) (4), (b) (6) | 28 Jan 2021 21:32:32 |

US3592229

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:21:23

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 09:45:13 |
| User entered 'breaths/min' | System | 28 Jan 2021 21:32:32 |

US3592229

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:21:23

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 09:45:13 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:37:55 |
| User entered '145' | (b) (4) (b) (4), (b) (6) | 28 Jan 2021 21:32:32 |

US3592229

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:21:23

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 09:45:13 |
| User entered 'mmHg' | System | 28 Jan 2021 21:32:32 |

US3592229

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 09:45:13 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:37:55 |
| User entered '98' | (b) (4) (b) (4), (b) (6) | 28 Jan 2021 21:32:32 |

US3592229

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:21:23

Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 09:45:13 |
| User entered 'mmHg' | System | 28 Jan 2021 21:32:32 |

US3592229

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

Form: Physical Examination

Generated On: 10 Jun 2021 08:21:23

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 09:45:13 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:37:55 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 28 Jan 2021 21:32:42 |

US3592229

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

Form: Physical Examination

Generated On: 10 Jun 2021 08:21:23

Date of examination (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 09:45:13 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:37:55 |
| User entered '25 Jan 2021' | (b) (4) (b) (4), (b) (6) | 28 Jan 2021 21:32:42 |

US3592229

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

Form: Exposure

Generated On: 10 Jun 2021 08:21:23

[Was study treatment given?](#)

| Audit | User | Time (GMT) |
|---|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 09:45:13 |
| User signature succeeded. | Terry Poling (b) (4) (b) (4) | 28 Apr 2021 09:37:55 |
| User closed query 'Was study treatment given? Is Yes but any of these is missing: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' (Site from System). | System | 28 Jan 2021 21:33:04 |
| Query 'Was study treatment given? Is Yes but any of these is missing: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' answered by data change (Site from System). | System | 28 Jan 2021 21:33:04 |
| User opened query 'Was study treatment given? Is Yes but any of these is missing: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' (Site from System). | System | 28 Jan 2021 21:32:58 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 28 Jan 2021 21:32:58 |

US3592229

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

Form: Exposure

Generated On: 10 Jun 2021 08:21:23

[If No, reason not given](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 09:45:13 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:37:55 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 28 Jan 2021 21:32:58 |

US3592229

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

Form: Exposure

Generated On: 10 Jun 2021 08:21:23

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) | 30 Apr 2021 09:45:13 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:37:55 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 28 Jan 2021 21:32:58 |

US3592229

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

Form: Exposure

Generated On: 10 Jun 2021 08:21:23

[What was the study treatment? \(Unblinded\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 09:45:13 |
| User entered 'mRNA-1273' | System | 28 Jan 2021 21:32:58 |
| DataPoint set to visible. | System | 28 Jan 2021 21:30:04 |

US3592229

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

Form: Exposure

Generated On: 10 Jun 2021 08:21:23

[What was the treatment date? \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 09:45:13 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:37:55 |
| User entered '25 Jan 2021' | (b) (4) (b) (4), (b) (6) | 28 Jan 2021 21:32:58 |

US3592229

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

Form: Exposure

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 09:45:13 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:37:55 |
| User entered '10:48' | (b) (4) (b) (4), (b) (6) | 28 Jan 2021 21:32:58 |

US3592229

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

Form: Exposure

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 09:45:13 |
| User entered '25 Jan 2021 10:48' | System | 28 Jan 2021 21:32:58 |

US3592229

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

Form: Exposure

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 09:45:13 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:37:55 |
| User entered 'Left Arm (LEFT ARM)' reason for change: Data Entry Error | (b) (4) (b) (4), (b) (6) | 28 Jan 2021 21:33:04 |
| User entered empty. | (b) (4), (b) (6) | 28 Jan 2021 21:32:58 |

US3592229

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

Form: Exposure

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 09:45:13 |
| User entered 'ONCE' | System | 28 Jan 2021 21:32:58 |

US3592229

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

Form: Exposure

Generated On: 10 Jun 2021 08:21:23

What was the route of administration for the study treatment?

| Audit | User | Time (GMT) |
|------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 09:45:13 |
| User entered 'INTRAMUSCULAR' | System | 28 Jan 2021 21:32:58 |

US3592229

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:21:23

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 09:45:13 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:37:55 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 28 Jan 2021 21:30:34 |

US3592229

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:21:23

Collection date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 09:45:13 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:37:55 |
| User entered '25 Jan 2021' | (b) (4) (b) (4), (b) (6) | 28 Jan 2021 21:30:34 |

US3592229

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:21:23

Collection time (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 09:45:13 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:37:55 |
| User entered '10:40' | (b) (4) (b) (4), (b) (6) | 28 Jan 2021 21:30:34 |

US3592229

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 09:45:13 |
| User entered '25 Jan 2021 10:40' | System | 28 Jan 2021 21:30:34 |

US3592229

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:21:23

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 09:45:13 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:37:55 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 28 Jan 2021 21:30:47 |

US3592229

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:21:23

Collection date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 09:45:13 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:37:55 |
| User entered '25 Jan 2021' | (b) (4) (b) (4), (b) (6) | 28 Jan 2021 21:30:47 |

US3592229

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:21:23

Collection time (00:00 - 23:59)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 09:45:13 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:37:55 |
| User entered '10:30' | (b) (4) (b) (4), (b) (6) | 28 Jan 2021 21:30:47 |

US3592229

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 09:45:13 |
| User entered '25 Jan 2021 10:30' | System | 28 Jan 2021 21:30:47 |

US3592229

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

Form: Continuing

Generated On: 10 Jun 2021 08:21:23

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 09:45:13 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:37:55 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 28 Jan 2021 21:30:54 |

US3592229

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

Form: Continuing

Generated On: 10 Jun 2021 08:21:23

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 09:45:13 |
| User entered 'I' | System | 28 Jan 2021 21:30:54 |

US3592229

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:21:23

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:02:11 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:37:55 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 01 Mar 2021 17:10:16 |

US3592229

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:21:23

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:02:11 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:37:55 |
| User entered '2 Feb 2021' | (b) (4) (b) (4), (b) (6) | 01 Mar 2021 17:10:16 |

US3592229

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:21:23

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:02:11 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:37:55 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4) (b) (4), (b) (6) | 01 Mar 2021 17:10:16 |

US3592229

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:21:23

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:02:11 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:37:55 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 01 Mar 2021 17:10:16 |

US3592229

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:21:23

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:02:11 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:37:55 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 01 Mar 2021 17:10:20 |

US3592229

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:21:23

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:02:11 |
| User entered 'l' | System | 01 Mar 2021 17:10:20 |

US3592229

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:21:23

[OLD29 Placebo Flag](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:02:11 |
| User entered 'I' | System | 01 Mar 2021 17:10:20 |
| DataPoint set to visible. | System | 01 Mar 2021 17:10:20 |

US3592229

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:21:23

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:54:53 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:36:00 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 01 Mar 2021 17:11:49 |

US3592229

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:54:53 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:36:00 |
| User entered '23 Feb 2021' | (b) (4) (b) (4), (b) (6) | 01 Mar 2021 17:11:49 |

US3592229

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|--------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:54:53 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:36:00 |
| User entered 'Clinic (Clinic)' | (b) (4) (b) (4), (b) (6) | 01 Mar 2021 17:11:49 |

US3592229

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:21:23

[Folder OID](#)

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:54:53 |
| User entered 'OLD29' | System | 01 Mar 2021 17:11:49 |

US3592229

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:21:23

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:54:53 |
| User accepted default value 'Pre-Dose (PREDOSE)' | (b) (4), (b) (6) | 13 Apr 2021 14:07:52 |

US3592229

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:21:23

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:54:53 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:36:00 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 13 Apr 2021 14:07:52 |

US3592229

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:21:23

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:54:53 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:36:00 |
| User entered '23 Feb 2021' | (b) (4) (b) (4), (b) (6) | 13 Apr 2021 14:07:52 |

US3592229

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:54:53 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:36:00 |
| User entered '13:14' | (b) (4) (b) (4), (b) (6) | 13 Apr 2021 14:07:52 |

US3592229

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:54:53 |
| User entered '23 Feb 2021 13:14' | System | 13 Apr 2021 14:07:52 |

US3592229

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:21:23

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:54:53 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:36:00 |
| User entered '36.9' C | (b) (4) (b) (4), (b) (6) | 13 Apr 2021 14:07:52 |

US3592229

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:21:23

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:54:53 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:36:00 |
| User entered 'Oral (Oral)' | (b) (4) (b) (4), (b) (6) | 13 Apr 2021 14:07:52 |

US3592229

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:21:23

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:54:53 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:36:00 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 13 Apr 2021 14:07:52 |

US3592229

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:21:23

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:54:53 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:36:00 |
| User entered '73' | (b) (4) (b) (4), (b) (6) | 13 Apr 2021 14:07:52 |

US3592229

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:21:23

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:54:53 |
| User entered 'bpm' | System | 13 Apr 2021 14:07:52 |

US3592229

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:54:53 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:36:00 |
| User entered '12' | (b) (4) (b) (4), (b) (6) | 13 Apr 2021 14:07:52 |

US3592229

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:21:23

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:54:53 |
| User entered 'breaths/min' | System | 13 Apr 2021 14:07:52 |

US3592229

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:21:23

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:54:53 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:36:00 |
| User entered '142' | (b) (4) (b) (4), (b) (6) | 13 Apr 2021 14:07:52 |

US3592229

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:21:23

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:54:53 |
| User entered 'mmHg' | System | 13 Apr 2021 14:07:52 |

US3592229

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:54:53 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:36:00 |
| User entered '90' | (b) (4) (b) (4), (b) (6) | 13 Apr 2021 14:07:52 |

US3592229

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:21:23

Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:54:53 |
| User entered 'mmHg' | System | 13 Apr 2021 14:07:52 |

US3592229

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:21:23

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:54:53 |
| User accepted default value 'Post-Dose (POSTDOSE)' | (b) (4), (b) (6) | 13 Apr 2021 14:07:52 |

US3592229

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:21:23

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:54:53 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:36:00 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 13 Apr 2021 14:07:52 |

US3592229

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:21:23

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:54:53 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:36:00 |
| User entered '23 Feb 2021' | (b) (4) (b) (4), (b) (6) | 13 Apr 2021 14:07:52 |

US3592229

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:54:53 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:36:00 |
| User entered '14:11' | (b) (4) (b) (4), (b) (6) | 13 Apr 2021 14:07:52 |

US3592229

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:54:53 |
| User entered '23 Feb 2021 14:11' | System | 13 Apr 2021 14:07:52 |

US3592229

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:21:23

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:54:53 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:36:00 |
| User closed query 'Temperature reported is out of range >41.7C (107F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System). | (b) (4) | 13 Apr 2021 14:09:29 |
| Query 'Temperature reported is out of range >41.7C (107F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered by data change (Site from System). | System | 13 Apr 2021 14:09:29 |
| User entered '98.4' F reason for change: Data Entry Error | (b) (4), (b) (6) | 13 Apr 2021 14:09:29 |
| User opened query 'Temperature reported is out of range >41.7C (107F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System). | System | 13 Apr 2021 14:07:52 |
| User entered '98.4' C | (b) (4), (b) (6) | 13 Apr 2021 14:07:52 |

US3592229

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:21:23

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:54:53 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:36:00 |
| User entered 'Oral (Oral)' | (b) (4) (b) (4), (b) (6) | 13 Apr 2021 14:07:52 |

US3592229

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:21:23

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:54:53 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:36:00 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 13 Apr 2021 14:07:52 |

US3592229

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:21:23

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:54:53 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:36:00 |
| User entered '80' | (b) (4) (b) (4), (b) (6) | 13 Apr 2021 14:07:52 |

US3592229

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:21:23

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:54:53 |
| User entered 'bpm' | System | 13 Apr 2021 14:07:52 |

US3592229

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:54:53 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:36:00 |
| User entered '16' | (b) (4) (b) (4), (b) (6) | 13 Apr 2021 14:07:52 |

US3592229

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:21:23

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:54:53 |
| User entered 'breaths/min' | System | 13 Apr 2021 14:07:52 |

US3592229

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:21:23

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:54:53 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:36:00 |
| User entered '135' | (b) (4) (b) (4), (b) (6) | 13 Apr 2021 14:07:52 |

US3592229

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:21:23

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:54:53 |
| User entered 'mmHg' | System | 13 Apr 2021 14:07:52 |

US3592229

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:21:23

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:54:53 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:36:00 |
| User entered '95' | (b) (4) (b) (4), (b) (6) | 13 Apr 2021 14:07:52 |

US3592229

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:21:23

Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:54:53 |
| User entered 'mmHg' | System | 13 Apr 2021 14:07:52 |

US3592229

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:21:23

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:54:53 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:36:00 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 01 Mar 2021 17:45:19 |

US3592229

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:21:23

Date of examination (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:54:53 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:36:00 |
| User entered '23 Feb 2021' | (b) (4) (b) (4), (b) (6) | 01 Mar 2021 17:45:19 |

US3592229

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:21:23

[Was study treatment given?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:54:53 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:36:00 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 01 Mar 2021 17:45:35 |

US3592229

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:21:23

[If No, reason not given](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:54:53 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:36:00 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 01 Mar 2021 17:45:35 |

US3592229

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:21:23

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) | 30 Apr 2021 17:54:53 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:36:00 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 01 Mar 2021 17:45:35 |

US3592229

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:21:23

[What was the study treatment? \(Unblinded\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:54:53 |
| User entered 'mRNA-1273' | System | 01 Mar 2021 17:45:35 |
| DataPoint set to visible. | System | 01 Mar 2021 17:10:20 |

US3592229

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:21:23

[What was the treatment date? \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:54:53 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:36:00 |
| User entered '23 Feb 2021' | (b) (4) (b) (4), (b) (6) | 01 Mar 2021 17:45:35 |

US3592229

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:54:53 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:36:00 |
| User entered '13:39' | (b) (4) (b) (4), (b) (6) | 01 Mar 2021 17:45:35 |

US3592229

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:54:53 |
| User entered '23 Feb 2021 13:39' | System | 01 Mar 2021 17:45:35 |

US3592229

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|------------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:54:53 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:36:00 |
| User entered 'Left Arm (LEFT ARM)' | (b) (4) (b) (4), (b) (6) | 01 Mar 2021 17:45:35 |

US3592229

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:54:53 |
| User entered 'ONCE' | System | 01 Mar 2021 17:45:35 |

US3592229

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:21:23

What was the route of administration for the study treatment?

| Audit | User | Time (GMT) |
|------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:54:53 |
| User entered 'INTRAMUSCULAR' | System | 01 Mar 2021 17:45:35 |

US3592229

Folder: OL-D29 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:21:23

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:54:53 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:36:00 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 01 Mar 2021 17:45:44 |

US3592229

Folder: OL-D29 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:21:23

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:54:53 |
| User entered 'l' | System | 01 Mar 2021 17:45:44 |

US3592229

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:21:23

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 07:54:41 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:37:55 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 08 Mar 2021 15:36:36 |

US3592229

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:21:23

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 07:54:41 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:37:55 |
| User entered '2 Mar 2021' | (b) (4) (b) (4), (b) (6) | 08 Mar 2021 15:36:36 |

US3592229

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:21:23

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 07:54:41 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:37:55 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4) (b) (4), (b) (6) | 08 Mar 2021 15:36:36 |

US3592229

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:21:23

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 07:54:41 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:37:55 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 08 Mar 2021 15:36:36 |

US3592229

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:21:23

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 07:54:41 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:37:55 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 08 Mar 2021 15:36:40 |

US3592229

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:21:23

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 07:54:41 |
| User entered 'l' | System | 08 Mar 2021 15:36:40 |

US3592229

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:21:23

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 03:43:01 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:36:00 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 22 Mar 2021 16:35:02 |

US3592229

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:21:23

Visit date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 03:43:01 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:36:00 |
| User closed query 'OL-D57 Visit Date is < 25 days or > 42 days after OL-D29 visit vaccination. Please reconcile or confirm dates.' (Site from System). | (b) (4) | |
| Query 'OL-D57 Visit Date is < 25 days or > 42 days after OL-D29 visit vaccination. Please reconcile or confirm dates.' answered with 'confirm visit date is correct, protocol deviation completed ' (Site from System). | (b) (4), (b) (6) | 12 Apr 2021 07:29:20 |
| Query 'OL-D57 Visit Date is < 25 days or > 42 days after OL-D29 visit vaccination. Please reconcile or confirm dates.' answered with 'confirm visit date is correct, protocol deviation completed ' (Site from System). | (b) (4), (b) (6) | 09 Apr 2021 18:59:53 |
| User opened query 'OL-D57 Visit Date is < 25 days or > 42 days after OL-D29 visit vaccination. Please reconcile or confirm dates.' (Site from System). | System | 22 Mar 2021 16:35:02 |
| User entered '19 Mar 2021' | (b) (4), (b) (6) | 22 Mar 2021 16:35:02 |

US3592229

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|--------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 03:43:01 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:36:00 |
| User entered 'Clinic (Clinic)' | (b) (4) (b) (4), (b) (6) | 22 Mar 2021 16:35:02 |

US3592229

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:21:23

[Folder OID](#)

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 03:43:01 |
| User entered 'OLD57' | System | 22 Mar 2021 16:35:02 |

US3592229

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:21:23

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 03:43:01 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:36:00 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 22 Mar 2021 16:36:04 |

US3592229

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:21:23

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 03:43:01 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:36:00 |
| User entered '19 Mar 2021' | (b) (4) (b) (4), (b) (6) | 22 Mar 2021 16:36:04 |

US3592229

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 03:43:01 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:36:00 |
| User entered '11:07' | (b) (4) (b) (4), (b) (6) | 22 Mar 2021 16:36:04 |

US3592229

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 03:43:01 |
| User entered '19 Mar 2021 11:07' | System | 22 Mar 2021 16:36:04 |

US3592229

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:21:23

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 03:43:01 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:36:00 |
| User entered '36.9' C | (b) (4) (b) (4), (b) (6) | 22 Mar 2021 16:36:04 |

US3592229

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:21:23

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 03:43:01 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:36:00 |
| User entered 'Oral (Oral)' | (b) (4) (b) (4), (b) (6) | 22 Mar 2021 16:36:04 |

US3592229

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:21:23

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 03:43:01 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:36:00 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 22 Mar 2021 16:36:04 |

US3592229

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:21:23

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 03:43:01 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:36:00 |
| User entered '62' | (b) (4) (b) (4), (b) (6) | 22 Mar 2021 16:36:04 |

US3592229

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:21:23

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 03:43:01 |
| User entered 'bpm' | System | 22 Mar 2021 16:36:04 |

US3592229

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 03:43:01 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:36:00 |
| User entered '16' | (b) (4) (b) (4), (b) (6) | 22 Mar 2021 16:36:04 |

US3592229

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:21:23

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 03:43:01 |
| User entered 'breaths/min' | System | 22 Mar 2021 16:36:04 |

US3592229

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:21:23

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 03:43:01 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:36:00 |
| User closed query 'Per CDM: Systolic blood pressure is out of range per protocol. Please indicate if CS or NCS and report as AE, if appropriate ' (Site from DM). | (b) (4) (b) (4), (b) (6) | 14 Apr 2021 06:32:41 |
| Query 'Per CDM: Systolic blood pressure is out of range per protocol. Please indicate if CS or NCS and report as AE, if appropriate ' answered with 'confirm value is correct, not clinically significant ' (Site from DM). | (b) (4), (b) (6) | 13 Apr 2021 14:20:36 |
| User opened query 'Per CDM: Systolic blood pressure is out of range per protocol. Please indicate if CS or NCS and report as AE, if appropriate ' (Site from DM). | (b) (4), (b) (6) | 29 Mar 2021 08:48:30 |
| User entered '159' | (b) (4), (b) (6) | 22 Mar 2021 16:36:04 |

US3592229

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:21:23

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 03:43:01 |
| User entered 'mmHg' | System | 22 Mar 2021 16:36:04 |

US3592229

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 03:43:01 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:36:00 |
| User entered '88' | (b) (4) (b) (4), (b) (6) | 22 Mar 2021 16:36:04 |

US3592229

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:21:23

[Diastolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 03:43:01 |
| User entered 'mmHg' | System | 22 Mar 2021 16:36:04 |

US3592229

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:21:23

[Height \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 03:43:01 |

US3592229

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:21:23

Weight (derived)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 03:43:01 |

US3592229

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:21:23

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 03:43:01 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:36:00 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 22 Mar 2021 16:35:20 |

US3592229

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:21:23

Date of examination (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 03:43:01 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:36:00 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 22 Mar 2021 16:35:20 |

US3592229

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:21:23

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 03:43:01 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:36:00 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 22 Mar 2021 16:35:32 |

US3592229

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:21:23

Collection date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 03:43:01 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:36:00 |
| User entered '19 Mar 2021' | (b) (4) (b) (4), (b) (6) | 22 Mar 2021 16:35:32 |

US3592229

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:21:23

Collection time (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 03:43:01 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:36:00 |
| User entered '11:38' | (b) (4) (b) (4), (b) (6) | 22 Mar 2021 16:35:32 |

US3592229

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 03:43:01 |
| User entered '19 Mar 2021 11:38' | System | 22 Mar 2021 16:35:32 |

US3592229

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 08:21:23

[Did the participant experience any adverse events?](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 10:46:45 |
| User signature succeeded. | Terry Poling (b) (4) | 16 Apr 2021 15:55:48 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | (b) (4) (b) (4), (b) (6) | 13 Sep 2020 17:03:18 |
| User entered 'No (N)' | (b) (4), (b) (6) | 03 Sep 2020 17:47:12 |

US3592229

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:21:23

[AEID](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 02:49:57 |

US3592229

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:21:23

[Adverse event](#)

| Audit | User | Time (GMT) |
|---|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 02:49:57 |
| User signature succeeded. | Terry Poling (b) (4) | 30 Apr 2021 15:49:11 |
| User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Urinary tract infections, PT: Urinary tract infection, LLT: Urinary tract infection - version MedDRA\23.0. | (b) (4) Coder Import (b) (4) (b) (4) | 13 Sep 2020 17:10:54 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0. | Coder Import (b) (4) (b) (4) | 13 Sep 2020 17:10:54 |
| Data point term sent to Coder | System | 13 Sep 2020 17:09:55 |
| User entered 'urinary tract infection' | (b) (4), (b) (6) | 13 Sep 2020 17:09:11 |

US3592229

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:21:23

[Was this a medically-attended AE?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 02:49:57 |
| User signature succeeded. | Terry Poling (b) (4) | 30 Apr 2021 15:49:11 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 13 Sep 2020 17:09:11 |

US3592229

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:21:23

[Was this a Solicited Adverse Reaction?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 02:49:57 |
| User signature succeeded. | Terry Poling (b) (4) | 30 Apr 2021 15:49:11 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 13 Sep 2020 17:09:11 |

US3592229

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:21:23

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 02:49:57 |
| User signature succeeded. | Terry Poling (b) (4) | 30 Apr 2021 15:49:11 |
| 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 | 23 Sep 2020 17:10:09 |
| User entered 'No (N)' reason for change: Data Entry Error | (b) (4), (b) (6) | 23 Sep 2020 17:10:09 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 13 Sep 2020 17:09:11 |
| User entered empty. | (b) (4), (b) (6) | 13 Sep 2020 17:09:11 |

US3592229

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:21:23

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 02:49:57 |
| User signature succeeded. | Terry Poling (b) (4) | 30 Apr 2021 15:49:11 |
| Amendment Manager: Query closed during migration process because the edit check no longer exists in target version. | (b) (4) | 17 Sep 2020 00:13:12 |
| User opened query 'Adverse Event Start Date is before treatment date at Visit 2. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' (Site from System). | System | 15 Sep 2020 13:14:32 |
| User entered '22 Aug 2020' | (b) (4), (b) (6) | 13 Sep 2020 17:09:11 |

US3592229

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:21:23

Start time (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 02:49:57 |
| User signature succeeded. | Terry Poling (b) (4) | 30 Apr 2021 15:49:11 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 13 Sep 2020 17:09:11 |

US3592229

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:21:23

[AE start date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 02:49:57 |
| User entered empty. | System | 13 Sep 2020 17:09:11 |

US3592229

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:21:23

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 02:49:57 |
| User signature succeeded. | Terry Poling (b) (4) | 30 Apr 2021 15:49:11 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 13 Sep 2020 17:09:11 |

US3592229

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:21:23

If not Ongoing, end date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 02:49:57 |
| User signature succeeded. | Terry Poling (b) (4) | 30 Apr 2021 15:49:11 |
| User entered '26 Aug 2020' | (b) (4) (b) (4), (b) (6) | 13 Sep 2020 17:09:11 |

US3592229

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:21:23

End time (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 02:49:57 |
| User signature succeeded. | Terry Poling (b) (4) | 30 Apr 2021 15:49:11 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 13 Sep 2020 17:09:11 |

US3592229

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:21:23

[AE End Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 02:49:57 |
| User entered empty. | System | 13 Sep 2020 17:09:11 |

US3592229

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:21:23

[Severity](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 02:49:57 |
| User signature succeeded. | Terry Poling (b) (4) | 30 Apr 2021 15:49:11 |
| User entered 'Grade 1/Mild (Grade 1/Mild)' | (b) (4) (b) (4), (b) (6) | 13 Sep 2020 17:09:11 |

US3592229

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:21:23

[Is the adverse event serious?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 02:49:57 |
| User signature succeeded. | Terry Poling (b) (4) | 30 Apr 2021 15:49:11 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 13 Sep 2020 17:09:11 |

US3592229

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:21:23

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 02:49:57 |
| User signature succeeded. | Terry Poling (b) (4) | 30 Apr 2021 15:49:11 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 13 Sep 2020 17:09:11 |

US3592229

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:21:23

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 02:49:57 |
| User signature succeeded. | Terry Poling (b) (4) | 30 Apr 2021 15:49:11 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 13 Sep 2020 17:09:11 |

US3592229

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:21:23

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 02:49:57 |
| User signature succeeded. | Terry Poling (b) (4) | 30 Apr 2021 15:49:11 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 13 Sep 2020 17:09:11 |

US3592229

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:21:23

Hospital Admission Date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 02:49:57 |
| User signature succeeded. | Terry Poling (b) (4) | 30 Apr 2021 15:49:11 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 13 Sep 2020 17:09:11 |

US3592229

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:21:23

Hospital Discharge Date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 02:49:57 |
| User signature succeeded. | Terry Poling (b) (4) | 30 Apr 2021 15:49:11 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 13 Sep 2020 17:09:11 |

US3592229

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:21:23

[Admitted to ICU?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 02:49:57 |
| User signature succeeded. | Terry Poling (b) (4) | 30 Apr 2021 15:49:11 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 13 Sep 2020 17:09:11 |

US3592229

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:21:23

[Number of Days in ICU](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 02:49:57 |
| User signature succeeded. | Terry Poling (b) (4) | 30 Apr 2021 15:49:11 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 13 Sep 2020 17:09:11 |

US3592229

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:21:23

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 02:49:57 |
| User signature succeeded. | Terry Poling (b) (4) | 30 Apr 2021 15:49:11 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 13 Sep 2020 17:09:11 |

US3592229

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:21:23

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 02:49:57 |
| User signature succeeded. | Terry Poling (b) (4) | 30 Apr 2021 15:49:11 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 13 Sep 2020 17:09:11 |

US3592229

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:21:23

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 02:49:57 |
| User signature succeeded. | Terry Poling (b) (4) | 30 Apr 2021 15:49:11 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 13 Sep 2020 17:09:11 |

US3592229

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:21:23

[Relationship to investigational product](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 02:49:57 |
| User signature succeeded. | Terry Poling (b) (4) | 30 Apr 2021 15:49:11 |
| User closed query 'Data is required. Please complete.' (Site from System). | (b) (4) | 23 Sep 2020 17:10:09 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 23 Sep 2020 17:10:09 |
| User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error | (b) (4), (b) (6) | 23 Sep 2020 17:10:09 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 13 Sep 2020 17:09:11 |
| User entered empty. | (b) (4), (b) (6) | 13 Sep 2020 17:09:11 |

US3592229

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:21:23

[Relationship to Study Procedure](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 02:49:57 |
| User signature succeeded. | Terry Poling (b) (4) | 30 Apr 2021 15:49:11 |
| User closed query 'Data is required. Please complete.' (Site from System). | (b) (4) | 23 Sep 2020 17:10:09 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 23 Sep 2020 17:10:09 |
| User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error | (b) (4), (b) (6) | 23 Sep 2020 17:10:09 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 13 Sep 2020 17:09:11 |
| User entered empty. | (b) (4), (b) (6) | 13 Sep 2020 17:09:11 |

US3592229

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:21:23

[Action taken with investigational product](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 02:49:57 |
| User signature succeeded. | Terry Poling (b) (4) | 30 Apr 2021 15:49:11 |
| User closed query 'Data is required. Please complete.' (Site from System). | (b) (4) | 23 Sep 2020 17:10:09 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 23 Sep 2020 17:10:09 |
| User entered 'None (NONE)' reason for change: Data Entry Error | (b) (4), (b) (6) | 23 Sep 2020 17:10:09 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 13 Sep 2020 17:09:11 |
| User entered empty. | (b) (4), (b) (6) | 13 Sep 2020 17:09:11 |

US3592229

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:21:23

[None](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 02:49:57 |
| User signature succeeded. | Terry Poling (b) (4) | 30 Apr 2021 15:49:11 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 13 Sep 2020 17:09:11 |

US3592229

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:21:23

[Concomitant Medication](#)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 02:49:57 |
| User signature succeeded. | Terry Poling (b) (4) | 30 Apr 2021 15:49:11 |
| User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM). | (b) (4) (b) (4), (b) (6) | 05 Oct 2020 12:17:36 |
| Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' answered with 'Concomitant medication added' (Site from DM). | (b) (4), (b) (6) | 01 Oct 2020 22:47:41 |
| User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM). | (b) (4), (b) (6) | 01 Oct 2020 08:10:59 |
| User entered 'I' | (b) (4), (b) (6) | 13 Sep 2020 17:09:11 |

US3592229

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:21:23

[Concomitant Procedure](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 02:49:57 |
| User signature succeeded. | Terry Poling (b) (4) | 30 Apr 2021 15:49:11 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 13 Sep 2020 17:09:11 |

US3592229

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:21:23

[Outcome](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 02:49:57 |
| User signature succeeded. | Terry Poling (b) (4) | 30 Apr 2021 15:49:11 |
| 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 | 23 Sep 2020 17:10:09 |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: | (b) (4), (b) (6) | 23 Sep 2020 17:10:09 |
| Data Entry Error | | |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 13 Sep 2020 17:09:11 |
| User entered empty. | (b) (4), (b) (6) | 13 Sep 2020 17:09:11 |

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:21:23

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 02:49:57 |
| User signature succeeded. | Terry Poling (b) (4) | 30 Apr 2021 15:49:11 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 13 Sep 2020 17:09:11 |

US3592229

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:21:23

[Narrative](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 02:49:57 |
| User signature succeeded. | Terry Poling (b) (4) | 30 Apr 2021 15:49:11 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 13 Sep 2020 17:09:11 |

US3592229

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:21:23

Serious Adverse Event Derived (CSA Programming Field Only)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 02:49:57 |
| User entered '0' | System | 13 Sep 2020 17:09:11 |

US3592229

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:21:23

Medically Attended AE Derived (CSA Programming Field Only)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 02:49:57 |
| User entered 'I' | System | 13 Sep 2020 17:09:11 |

US3592229

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:21:23

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 02:49:57 |

US3592229

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:21:23

[AEID](#)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| User signature succeeded. | Terry Poling (b) (4) | 30 Apr 2021 15:49:11 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 22 Mar 2021 18:06:34 |
| User entered 'USA-US103-2021-mRNA-1273-P301000006' | System | 22 Mar 2021 18:06:30 |
| User entered 'New' | (b) (4), (b) (6) | 22 Mar 2021 18:06:30 |

US3592229

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:21:23

[Adverse event](#)

| Audit | User | Time (GMT) |
|---|---------------------------------|----------------------|
| User signature succeeded. | Terry Poling (b) (4) | 30 Apr 2021 15:49:11 |
| User coded data point as SOC: Reproductive system and breast disorders, HLGT: Uterine, pelvic and broad ligament disorders, HLT: Uterine disorders NEC, PT: Endometrial hyperplasia, LLT: Atypical hyperplasia of endometrium - version MedDRA\\23.0. | (b) (4) Coder Import (b) (4) | 25 Mar 2021 07:44:49 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0. | Coder Import (b) (4) | 25 Mar 2021 07:44:49 |
| Data point term sent to Coder | System | 19 Mar 2021 21:40:15 |
| User entered 'Atypical complex hyperplasia' | (b) (4), (b) (6) | 19 Mar 2021 21:39:26 |

US3592229

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:21:23

[Was this a medically-attended AE?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Terry Poling (b) (4) | 30 Apr 2021 15:49:11 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 19 Mar 2021 21:39:26 |

US3592229

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:21:23

[Was this a Solicited Adverse Reaction?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Terry Poling (b) (4) | 30 Apr 2021 15:49:11 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 19 Mar 2021 21:39:26 |

US3592229

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:21:23

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Terry Poling (b) (4) | 30 Apr 2021 15:49:11 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 19 Mar 2021 21:39:26 |

US3592229

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:21:23

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded. | Terry Poling (b) (4) | 30 Apr 2021 15:49:11 |
| User entered '19 Nov 2020' | (b) (4) (b) (4), (b) (6) | 19 Mar 2021 21:39:26 |

US3592229

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:21:23

Start time (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Terry Poling (b) (4) | 30 Apr 2021 15:49:11 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 19 Mar 2021 21:39:26 |

US3592229

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:21:23

[AE start date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 19 Mar 2021 21:39:26 |

US3592229

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:21:23

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Terry Poling (b) (4) | 30 Apr 2021 15:49:11 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 19 Mar 2021 21:39:26 |

US3592229

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:21:23

If not Ongoing, end date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded. | Terry Poling (b) (4) | 30 Apr 2021 15:49:11 |
| User entered '16 Mar 2021' | (b) (4) (b) (4), (b) (6) | 19 Mar 2021 21:39:26 |

US3592229

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:21:23

End time (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Terry Poling (b) (4) | 30 Apr 2021 15:49:11 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 19 Mar 2021 21:39:26 |

US3592229

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:21:23

[AE End Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 19 Mar 2021 21:39:26 |

US3592229

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:21:23

[Severity](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| User signature succeeded. | Terry Poling (b) (4) | 30 Apr 2021 15:49:11 |
| User entered 'Grade 3/Severe (Grade 3/Severe)' | (b) (4) (b) (4), (b) (6) | 19 Mar 2021 21:39:26 |

US3592229

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:21:23

[Is the adverse event serious?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Terry Poling (b) (4) | 30 Apr 2021 15:49:11 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 19 Mar 2021 21:39:26 |

US3592229

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:21:23

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Terry Poling (b) (4) | 30 Apr 2021 15:49:11 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 19 Mar 2021 21:39:26 |

US3592229

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:21:23

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Terry Poling (b) (4) | 30 Apr 2021 15:49:11 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 19 Mar 2021 21:39:26 |

US3592229

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:21:23

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Terry Poling (b) (4) | 30 Apr 2021 15:49:11 |
| User entered 'I' | (b) (4) (b) (4), (b) (6) | 19 Mar 2021 21:39:26 |

US3592229

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:21:23

Hospital Admission Date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded. | Terry Poling (b) (4) | 30 Apr 2021 15:49:11 |
| User entered '16 Mar 2021' | (b) (4) (b) (4), (b) (6) | 19 Mar 2021 21:39:26 |

US3592229

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:21:23

Hospital Discharge Date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded. | Terry Poling (b) (4) | 30 Apr 2021 15:49:11 |
| User entered '17 Mar 2021' | (b) (4) (b) (4), (b) (6) | 19 Mar 2021 21:39:26 |

US3592229

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:21:23

[Admitted to ICU?](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| User signature succeeded. | Terry Poling (b) (4) | 30 Apr 2021 15:49:11 |
| User closed query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System). | (b) (4) System | 22 Mar 2021 16:34:39 |
| Query 'Admitted to ICU? is Unknown. However, this System data must be collected. Please leave this query open until the response can be updated to Yes or No.' answered by data change (Site from System). | | 22 Mar 2021 16:34:39 |
| User entered 'No (N)' reason for change: Data Entry Error | (b) (4), (b) (6) | 22 Mar 2021 16:34:39 |
| User opened query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System). | System | 19 Mar 2021 21:39:26 |
| User entered 'Unknown (UNK)' | (b) (4), (b) (6) | 19 Mar 2021 21:39:26 |

US3592229

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:21:23

[Number of Days in ICU](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Terry Poling (b) (4) | 30 Apr 2021 15:49:11 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 19 Mar 2021 21:39:26 |

US3592229

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:21:23

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Terry Poling (b) (4) | 30 Apr 2021 15:49:11 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 19 Mar 2021 21:39:26 |

US3592229

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:21:23

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Terry Poling (b) (4) | 30 Apr 2021 15:49:11 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 19 Mar 2021 21:39:26 |

US3592229

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:21:23

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Terry Poling (b) (4) | 30 Apr 2021 15:49:11 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 19 Mar 2021 21:39:26 |

US3592229

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:21:23

[Relationship to investigational product](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| User signature succeeded. | Terry Poling (b) (4) | 30 Apr 2021 15:49:11 |
| User entered 'Not Related (NOT RELATED)' | (b) (4) (b) (4), (b) (6) | 19 Mar 2021 21:39:26 |

US3592229

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:21:23

[Relationship to Study Procedure](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| User signature succeeded. | Terry Poling (b) (4) | 30 Apr 2021 15:49:11 |
| User entered 'Not Related (NOT RELATED)' | (b) (4) (b) (4), (b) (6) | 19 Mar 2021 21:39:26 |

US3592229

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:21:23

[Action taken with investigational product](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| User signature succeeded. | Terry Poling (b) (4) | 30 Apr 2021 15:49:11 |
| User entered 'Not Applicable (NOT APPLICABLE)' | (b) (4) (b) (4), (b) (6) | 19 Mar 2021 21:39:26 |

US3592229

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:21:23

None

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Terry Poling (b) (4) | 30 Apr 2021 15:49:11 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 19 Mar 2021 21:39:26 |

US3592229

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:21:23

[Concomitant Medication](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Terry Poling (b) (4) | 30 Apr 2021 15:49:11 |
| User entered 'l' | (b) (4) (b) (4), (b) (6) | 19 Mar 2021 21:39:26 |

US3592229

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:21:23

[Concomitant Procedure](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Terry Poling (b) (4) | 30 Apr 2021 15:49:11 |
| User entered 'l' | (b) (4) (b) (4), (b) (6) | 19 Mar 2021 21:39:26 |

US3592229

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:21:23

[Outcome](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| User signature succeeded. | Terry Poling (b) (4) | 30 Apr 2021 15:49:11 |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' | (b) (4) (b) (4), (b) (6) | 19 Mar 2021 21:39:26 |

US3592229

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:21:23

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Terry Poling (b) (4) | 30 Apr 2021 15:49:11 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 19 Mar 2021 21:39:26 |

US3592229

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:21:23

[Narrative](#)

| Audit | User | Time (GMT) |
|--|---|--|
| User closed query ' 1. PV Query: Please provide treatment medications given for the event. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so. ' (Site from Safety). User signature succeeded. | (b) (4), (b) (6) | 30 Apr 2021 19:24:38 |
| User entered 'SUBJECT WAS DIAGNOSED WITH AN ATYPICAL COMPLEX HYPERPLASIA IN NOVEMBER DURING WELL WOMAN EXAM. SUBJECT HAD hysterectomy TO RESOLVE ATYPICAL COMPLEX HYPERPLASIA AND STAYED OVERNIGHT IN HOSPITAL ON 03/16/2021. WILL UPDATED AS MEDICAL RECORDS AND INFORMATION BECOMES AVAILABLE.' reason for change: New Information Query ' | Terry Poling (b) (4) (b) (4) (b) (4), (b) (6) | 30 Apr 2021 15:49:11 30 Apr 2021 14:31:14 |
| 1. PV Query: Please provide treatment medications given for the event. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so. ' answered with 'medication and procedure page has been updated ' (Site from Safety). | (b) (4), (b) (6) | 30 Apr 2021 14:29:46 |
| User opened query ' 1. PV Query: Please provide treatment medications given for the event. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so. ' (Site from Safety). | (b) (4), (b) (6) | 29 Mar 2021 18:06:52 |
| User entered 'Subject was diagnosed with an atypical complex hyperplasia in November during well woman exam. Subject had hysterotomy to resolve atypical complex hyperplasia and stayed overnight in hospital on 03/16/2021. Will updated as medical records and information becomes available.' | (b) (4), (b) (6) | 19 Mar 2021 21:39:26 |

US3592229

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:21:23

Serious Adverse Event Derived (CSA Programming Field Only)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'l' | System | 19 Mar 2021 21:39:26 |

US3592229

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:21:23

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'l' | System | 19 Mar 2021 21:39:26 |

US3592229

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:21:23

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '0' | System | 19 Mar 2021 21:39:26 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 08:21:23

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

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 03:45:14 |
| User signature succeeded. | Terry Poling (b) (4) | 03 May 2021 19:54:33 |
| User closed query 'Per ETRTR: According to SAE page "Atypical Complex Hyperplasia", medication was given for SAE, but the same is missing in this folder. Please add Medications dosing details for SAE or reconcile otherwise, thanks.' (Site from CRA). | (b) (4) (b) (4), (b) (6) | 03 May 2021 12:38:26 |
| Query 'Per ETRTR: According to SAE page "Atypical Complex Hyperplasia", medication was given for SAE, but the same is missing in this folder. Please add Medications dosing details for SAE or reconcile otherwise, thanks.' answered with 'medication and procedure has been updated in EDC' (Site from CRA). | (b) (4), (b) (6) | 30 Apr 2021 14:33:57 |
| User opened query 'Per ETRTR: According to SAE page "Atypical Complex Hyperplasia", medication was given for SAE, but the same is missing in this folder. Please add Medications dosing details for SAE or reconcile otherwise, thanks.' (Site from CRA). | (b) (4), (b) (6) | 23 Mar 2021 22:46:00 |
| User closed query 'Per DM CLR: Per Diary Dose 1 Day 6, Headache (General) = Any use of prescription pain reliever or prevents daily 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) | 10 Mar 2021 02:24:30 |
| Query 'Per DM CLR: Per Diary Dose 1 Day 6, Headache (General) = Any use of prescription pain reliever or prevents daily 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 'per subject at time of dairy review subject took no medication for headache.' (Site from DM). | (b) (4), (b) (6) | 08 Mar 2021 22:09:32 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 08:21:23

[Were any prior/concomitant medications and/or vaccinations taken?](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| User opened query 'Per DM CLR: Per Diary Dose 1 Day 6, Headache (General) = Any use of prescription pain reliever or prevents daily 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) | 09 Feb 2021 09:26:28 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 19 Aug 2020 22:54:31 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:21:23

[Name of Medication](#)

| Audit | User | Time (GMT) |
|---|---------------------------------|----------------------|
| User signature succeeded. | Terry Poling (b) (4) | 16 Apr 2021 15:55:48 |
| User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: SELECTIVE SEROTONIN REUPTAKE INHIBITORS, PRODUCT: PAROXETINE - version WHODrug-Global-B3\\202003. | (b) (4) Coder Import (b) (4) | 19 Aug 2020 22:57:16 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 19 Aug 2020 22:57:16 |
| Data point term sent to Coder | System | 19 Aug 2020 22:56:19 |
| User entered 'paroxetine' | (b) (4), (b) (6) | 19 Aug 2020 22:55:44 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:21:23

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Terry Poling (b) (4) | 16 Apr 2021 15:55:48 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 19 Aug 2020 22:55:44 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:21:23

[Indication](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Terry Poling (b) (4) | 16 Apr 2021 15:55:48 |
| User entered 'depression' | (b) (4) (b) (4), (b) (6) | 19 Aug 2020 22:55:44 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:21:23

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Terry Poling (b) (4) | 16 Apr 2021 15:55:48 |
| User entered '10' | (b) (4) (b) (4), (b) (6) | 19 Aug 2020 22:55:44 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:21:23

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Terry Poling (b) (4) | 16 Apr 2021 15:55:48 |
| User entered 'mg (mg)' | (b) (4) (b) (4), (b) (6) | 19 Aug 2020 22:55:44 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:21:23

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Terry Poling (b) (4) | 16 Apr 2021 15:55:48 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 19 Aug 2020 22:55:44 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:21:23

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|-----------------------------|----------------------|
| User signature succeeded. | Terry Poling (b) (4) | 16 Apr 2021 15:55:48 |
| User entered 'once daily (QD)' | (b) (4) (b) (4), (b) (6) | 19 Aug 2020 22:55:44 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:21:23

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Terry Poling (b) (4) | 16 Apr 2021 15:55:48 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 19 Aug 2020 22:55:44 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:21:23

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded. | Terry Poling (b) (4) | 16 Apr 2021 15:55:48 |
| User entered 'Oral (ORAL)' | (b) (4) (b) (4), (b) (6) | 19 Aug 2020 22:55:44 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:21:23

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Terry Poling (b) (4) | 16 Apr 2021 15:55:48 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 19 Aug 2020 22:55:44 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:21:23

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| User signature succeeded. | Terry Poling (b) (4) | 16 Apr 2021 15:55:48 |
| User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). | (b) (4) (b) (4), (b) (6) | 20 Aug 2020 09:52:53 |
| 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.' | (b) (4), (b) (6) | 19 Aug 2020 22:55:56 |
| answered with 'entry is correct' (Site from System). | | |
| 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 | 19 Aug 2020 22:55:44 |
| User entered 'un Jan 2017' | (b) (4), (b) (6) | 19 Aug 2020 22:55:44 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:21:23

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Terry Poling (b) (4) | 16 Apr 2021 15:55:48 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 19 Aug 2020 22:55:44 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:21:23

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Terry Poling (b) (4) | 16 Apr 2021 15:55:48 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 19 Aug 2020 22:55:44 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:21:23

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Terry Poling (b) (4) | 16 Apr 2021 15:55:48 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 19 Aug 2020 22:55:44 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:21:23

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Terry Poling (b) (4) | 16 Apr 2021 15:55:48 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 19 Aug 2020 22:55:44 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:21:23

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'l' | System | 19 Aug 2020 22:55:44 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:21:23

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 19 Aug 2020 22:55:44 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:21:23

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 19 Aug 2020 22:55:44 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:21:23

[Name of Medication](#)

| Audit | User | Time (GMT) |
|---|---------------------------------|----------------------|
| User signature succeeded. | Terry Poling (b) (4) | 16 Apr 2021 15:55:48 |
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: PANTOPRAZOLE - version WHODrug-Global-B3\\202003. | (b) (4) Coder Import (b) (4) | 19 Aug 2020 23:00:07 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 19 Aug 2020 23:00:07 |
| Data point term sent to Coder | System | 19 Aug 2020 22:59:29 |
| User entered 'pantoprazole' | (b) (4), (b) (6) | 19 Aug 2020 22:59:10 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:21:23

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Terry Poling (b) (4) | 16 Apr 2021 15:55:48 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 19 Aug 2020 22:59:10 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:21:23

[Indication](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| User signature succeeded. | Terry Poling (b) (4) | 16 Apr 2021 15:55:48 |
| User entered 'gastroesophageal reflux disease' | (b) (4) (b) (4), (b) (6) | 19 Aug 2020 22:59:10 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:21:23

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Terry Poling (b) (4) | 16 Apr 2021 15:55:48 |
| User entered '40' | (b) (4) (b) (4), (b) (6) | 19 Aug 2020 22:59:10 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:21:23

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Terry Poling (b) (4) | 16 Apr 2021 15:55:48 |
| User entered 'mg (mg)' | (b) (4) (b) (4), (b) (6) | 19 Aug 2020 22:59:10 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:21:23

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Terry Poling (b) (4) | 16 Apr 2021 15:55:48 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 19 Aug 2020 22:59:10 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:21:23

[Frequency](#)

| Audit | User | Time (GMT) |
|----------------------------------|-----------------------------|----------------------|
| User signature succeeded. | Terry Poling (b) (4) | 16 Apr 2021 15:55:48 |
| User entered 'twice daily (BID)' | (b) (4) (b) (4), (b) (6) | 19 Aug 2020 22:59:10 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:21:23

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Terry Poling (b) (4) | 16 Apr 2021 15:55:48 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 19 Aug 2020 22:59:10 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:21:23

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded. | Terry Poling (b) (4) | 16 Apr 2021 15:55:48 |
| User entered 'Oral (ORAL)' | (b) (4) (b) (4), (b) (6) | 19 Aug 2020 22:59:10 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:21:23

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Terry Poling (b) (4) | 16 Apr 2021 15:55:48 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 19 Aug 2020 22:59:10 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:21:23

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| User signature succeeded. | Terry Poling (b) (4) | 16 Apr 2021 15:55:48 |
| User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). | (b) (4) (b) (4), (b) (6) | 20 Aug 2020 09:52:59 |
| Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'entry is correct' (Site from System). | (b) (4), (b) (6) | 19 Aug 2020 22:59:25 |
| 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 | 19 Aug 2020 22:59:10 |
| User entered 'un Mar 2018' | (b) (4), (b) (6) | 19 Aug 2020 22:59:10 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:21:23

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Terry Poling (b) (4) | 16 Apr 2021 15:55:48 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 19 Aug 2020 22:59:10 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:21:23

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Terry Poling (b) (4) | 16 Apr 2021 15:55:48 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 19 Aug 2020 22:59:10 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:21:23

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Terry Poling (b) (4) | 16 Apr 2021 15:55:48 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 19 Aug 2020 22:59:10 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:21:23

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Terry Poling (b) (4) | 16 Apr 2021 15:55:48 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 19 Aug 2020 22:59:10 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:21:23

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '2' | System | 19 Aug 2020 22:59:10 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:21:23

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'l' | System | 19 Aug 2020 22:59:10 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:21:23

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 19 Aug 2020 22:59:10 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:21:23

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| User signature succeeded. | Terry Poling (b) (4) | 16 Apr 2021 15:55:48 |
| User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: PSYCHOSTIMULANTS, AGENTS USED FOR ADHD AND NOOTROPICS, ATC: CENTRALLY ACTING SYMPATHOMIMETICS, PRODUCT: DEXAMFETAMINE SULFATE, PRODUCTSYNONYM: DEXAMPHETAMINE - version WHODrug-Global-B3\\202003. | (b) (4) Coder Import (b) (4) | 01 Sep 2020 06:21:40 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 01 Sep 2020 06:21:40 |
| Data point term sent to Coder | System | 19 Aug 2020 23:01:34 |
| User entered 'D-amphetamine er' | (b) (4), (b) (6) | 19 Aug 2020 23:01:32 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:21:23

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Terry Poling (b) (4) | 16 Apr 2021 15:55:48 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 19 Aug 2020 23:01:32 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:21:23

[Indication](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| User signature succeeded. | Terry Poling (b) (4) | 16 Apr 2021 15:55:48 |
| User entered 'attention deficiency disorder' | (b) (4) (b) (4), (b) (6) | 19 Aug 2020 23:01:32 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:21:23

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Terry Poling (b) (4) | 16 Apr 2021 15:55:48 |
| User entered '30' | (b) (4) (b) (4), (b) (6) | 19 Aug 2020 23:01:32 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:21:23

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Terry Poling (b) (4) | 16 Apr 2021 15:55:48 |
| User entered 'mg (mg)' | (b) (4) (b) (4), (b) (6) | 19 Aug 2020 23:01:32 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:21:23

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Terry Poling (b) (4) | 16 Apr 2021 15:55:48 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 19 Aug 2020 23:01:32 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:21:23

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|-----------------------------|----------------------|
| User signature succeeded. | Terry Poling (b) (4) | 16 Apr 2021 15:55:48 |
| User entered 'once daily (QD)' | (b) (4) (b) (4), (b) (6) | 19 Aug 2020 23:01:32 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:21:23

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Terry Poling (b) (4) | 16 Apr 2021 15:55:48 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 19 Aug 2020 23:01:32 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:21:23

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded. | Terry Poling (b) (4) | 16 Apr 2021 15:55:48 |
| User entered 'Oral (ORAL)' | (b) (4) (b) (4), (b) (6) | 19 Aug 2020 23:01:32 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:21:23

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Terry Poling (b) (4) | 16 Apr 2021 15:55:48 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 19 Aug 2020 23:01:32 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:21:23

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| User signature succeeded. | Terry Poling (b) (4) | 16 Apr 2021 15:55:48 |
| User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). | (b) (4) (b) (4), (b) (6) | 20 Aug 2020 09:53:11 |
| 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 'entry is correct' (Site from System). | (b) (4), (b) (6) | 19 Aug 2020 23:01:42 |
| 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 | 19 Aug 2020 23:01:32 |
| User entered 'un Mar 2014' | (b) (4), (b) (6) | 19 Aug 2020 23:01:32 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:21:23

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Terry Poling (b) (4) | 16 Apr 2021 15:55:48 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 19 Aug 2020 23:01:32 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:21:23

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Terry Poling (b) (4) | 16 Apr 2021 15:55:48 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 19 Aug 2020 23:01:32 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:21:23

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Terry Poling (b) (4) | 16 Apr 2021 15:55:48 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 19 Aug 2020 23:01:32 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:21:23

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Terry Poling (b) (4) | 16 Apr 2021 15:55:48 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 19 Aug 2020 23:01:32 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:21:23

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'l' | System | 19 Aug 2020 23:01:32 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:21:23

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 19 Aug 2020 23:01:32 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:21:23

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 19 Aug 2020 23:01:32 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:21:23

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--|---------------------------------|----------------------|
| User signature succeeded. | Terry Poling (b) (4) | 16 Apr 2021 15:55:48 |
| User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: PSYCHOSTIMULANTS, AGENTS USED FOR ADHD AND NOOTROPICS, ATC: CENTRALLY ACTING SYMPATHOMIMETICS, PRODUCT: AMFETAMINE, PRODUCTSYNONYM: AMPHETAMINE - version WHODrug-Global-B3\\202003. | (b) (4) Coder Import (b) (4) | 19 Aug 2020 23:04:11 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 19 Aug 2020 23:04:11 |
| Data point term sent to Coder | System | 19 Aug 2020 23:03:38 |
| User entered 'amphetamine' | (b) (4), (b) (6) | 19 Aug 2020 23:03:25 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:21:23

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Terry Poling (b) (4) | 16 Apr 2021 15:55:48 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 19 Aug 2020 23:03:25 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:21:23

[Indication](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| User signature succeeded. | Terry Poling (b) (4) | 16 Apr 2021 15:55:48 |
| User entered 'Attention deficiency disorder' | (b) (4) (b) (4), (b) (6) | 19 Aug 2020 23:03:25 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:21:23

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Terry Poling (b) (4) | 16 Apr 2021 15:55:48 |
| User entered '30' | (b) (4) (b) (4), (b) (6) | 19 Aug 2020 23:03:25 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:21:23

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Terry Poling (b) (4) | 16 Apr 2021 15:55:48 |
| User entered 'mg (mg)' | (b) (4) (b) (4), (b) (6) | 19 Aug 2020 23:03:25 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:21:23

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Terry Poling (b) (4) | 16 Apr 2021 15:55:48 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 19 Aug 2020 23:03:25 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:21:23

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|-----------------------------|----------------------|
| User signature succeeded. | Terry Poling (b) (4) | 16 Apr 2021 15:55:48 |
| User entered 'once daily (QD)' | (b) (4) (b) (4), (b) (6) | 19 Aug 2020 23:03:25 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:21:23

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Terry Poling (b) (4) | 16 Apr 2021 15:55:48 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 19 Aug 2020 23:03:25 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:21:23

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded. | Terry Poling (b) (4) | 16 Apr 2021 15:55:48 |
| User entered 'Oral (ORAL)' | (b) (4) (b) (4), (b) (6) | 19 Aug 2020 23:03:25 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:21:23

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Terry Poling (b) (4) | 16 Apr 2021 15:55:48 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 19 Aug 2020 23:03:25 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:21:23

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| User signature succeeded. | Terry Poling (b) (4) | 16 Apr 2021 15:55:48 |
| User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). | (b) (4) (b) (4), (b) (6) | 20 Aug 2020 09:53:17 |
| 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.' | (b) (4), (b) (6) | 19 Aug 2020 23:03:35 |
| answered with 'entry is correct' (Site from System). | | |
| 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 | 19 Aug 2020 23:03:25 |
| User entered 'un Mar 2014' | (b) (4), (b) (6) | 19 Aug 2020 23:03:25 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:21:23

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Terry Poling (b) (4) | 16 Apr 2021 15:55:48 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 19 Aug 2020 23:03:25 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:21:23

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Terry Poling (b) (4) | 16 Apr 2021 15:55:48 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 19 Aug 2020 23:03:25 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:21:23

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Terry Poling (b) (4) | 16 Apr 2021 15:55:48 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 19 Aug 2020 23:03:25 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:21:23

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Terry Poling (b) (4) | 16 Apr 2021 15:55:48 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 19 Aug 2020 23:03:25 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:21:23

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'l' | System | 19 Aug 2020 23:03:25 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:21:23

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 19 Aug 2020 23:03:25 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:21:23

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 19 Aug 2020 23:03:25 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:21:23

[Name of Medication](#)

| Audit | User | Time (GMT) |
|---|--|----------------------|
| User signature succeeded. | Terry Poling (b) (4) | 16 Apr 2021 15:55:48 |
| User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: SIMVASTATIN - version WHODrug-Global-B3\\202003. | (b) (4) Coder Import (b) (4) (b) (4) | 19 Aug 2020 23:06:33 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 19 Aug 2020 23:06:33 |
| Data point term sent to Coder | System | 19 Aug 2020 23:05:47 |
| User entered 'simvastatin' | (b) (4), (b) (6) | 19 Aug 2020 23:04:59 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:21:23

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Terry Poling (b) (4) | 16 Apr 2021 15:55:48 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 19 Aug 2020 23:04:59 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:21:23

[Indication](#)

| Audit | User | Time (GMT) |
|-------------------------------------|-----------------------------|----------------------|
| User signature succeeded. | Terry Poling (b) (4) | 16 Apr 2021 15:55:48 |
| User entered 'hypercholesterolemia' | (b) (4) (b) (4), (b) (6) | 19 Aug 2020 23:04:59 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:21:23

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Terry Poling (b) (4) | 16 Apr 2021 15:55:48 |
| User entered '20' | (b) (4) (b) (4), (b) (6) | 19 Aug 2020 23:04:59 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:21:23

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Terry Poling (b) (4) | 16 Apr 2021 15:55:48 |
| User entered 'mg (mg)' | (b) (4) (b) (4), (b) (6) | 19 Aug 2020 23:04:59 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:21:23

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Terry Poling (b) (4) | 16 Apr 2021 15:55:48 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 19 Aug 2020 23:04:59 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:21:23

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|-----------------------------|----------------------|
| User signature succeeded. | Terry Poling (b) (4) | 16 Apr 2021 15:55:48 |
| User entered 'once daily (QD)' | (b) (4) (b) (4), (b) (6) | 19 Aug 2020 23:04:59 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:21:23

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Terry Poling (b) (4) | 16 Apr 2021 15:55:48 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 19 Aug 2020 23:04:59 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:21:23

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded. | Terry Poling (b) (4) | 16 Apr 2021 15:55:48 |
| User entered 'Oral (ORAL)' | (b) (4) (b) (4), (b) (6) | 19 Aug 2020 23:04:59 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:21:23

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Terry Poling (b) (4) | 16 Apr 2021 15:55:48 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 19 Aug 2020 23:04:59 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:21:23

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| User signature succeeded. | Terry Poling (b) (4) | 16 Apr 2021 15:55:48 |
| User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). | (b) (4) (b) (4), (b) (6) | 20 Aug 2020 09:53:23 |
| Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'entry is correct' (Site from System). | (b) (4), (b) (6) | 19 Aug 2020 23:05:54 |
| 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 | 19 Aug 2020 23:05:41 |
| User closed query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System). | System | 19 Aug 2020 23:05:41 |
| User entered 'un Jan 2014' reason for change: Data Entry Error | (b) (4), (b) (6) | 19 Aug 2020 23:05:41 |
| User opened query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System). | System | 19 Aug 2020 23:04:59 |
| User entered empty. | (b) (4), (b) (6) | 19 Aug 2020 23:04:59 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:21:23

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Terry Poling (b) (4) | 16 Apr 2021 15:55:48 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 19 Aug 2020 23:04:59 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:21:23

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Terry Poling (b) (4) | 16 Apr 2021 15:55:48 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 19 Aug 2020 23:04:59 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:21:23

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---|----------------------|----------------------|
| User signature succeeded. | Terry Poling (b) (4) | 16 Apr 2021 15:55:48 |
| | (b) (4) | |
| User closed query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System). | System | 19 Aug 2020 23:05:41 |
| User entered empty; reason for change Data Entry Error | (b) (4), (b) (6) | 19 Aug 2020 23:05:41 |
| User opened query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System). | System | 19 Aug 2020 23:04:59 |
| User entered 'un Jan 2014' | (b) (4), (b) (6) | 19 Aug 2020 23:04:59 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:21:23

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Terry Poling (b) (4) | 16 Apr 2021 15:55:48 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 19 Aug 2020 23:04:59 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:21:23

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'l' | System | 19 Aug 2020 23:04:59 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:21:23

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 19 Aug 2020 23:04:59 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:21:23

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 19 Aug 2020 23:04:59 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:21:23

[Name of Medication](#)

| Audit | User | Time (GMT) |
|---|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:06:31 |
| User signature succeeded. | Terry Poling (b) (4) | 16 Apr 2021 15:55:48 |
| User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), COMBINATIONS, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS) AND DIURETICS, PRODUCT: HYDROCHLOROTHIAZIDE;IRBESARTAN, PRODUCTSYNONYM: IRBESARTAN HYDROCHLOROTHIAZIDE - version WHODrug-Global-B3\\202003. | (b) (4) Coder Import (b) (4) (b) (4) | 13 Sep 2020 17:14:46 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 13 Sep 2020 17:14:46 |
| Data point term sent to Coder | System | 13 Sep 2020 17:13:55 |
| User entered 'irbesartan hydrochlorothiazide' | (b) (4), (b) (6) | 13 Sep 2020 17:13:13 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:21:23

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:06:31 |
| User signature succeeded. | Terry Poling (b) (4) | 16 Apr 2021 15:55:48 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 13 Sep 2020 17:13:13 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:21:23

[Indication](#)

| Audit | User | Time (GMT) |
|-----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:06:31 |
| User signature succeeded. | Terry Poling (b) (4) | 16 Apr 2021 15:55:48 |
| User entered 'hypertension' | (b) (4) (b) (4), (b) (6) | 13 Sep 2020 17:13:13 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:21:23

[Dose per administration](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:06:31 |
| User signature succeeded. | Terry Poling (b) (4) | 16 Apr 2021 15:55:48 |
| User closed query 'Per DM CLR: Please note this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components. ' (Site from DM). | (b) (4) (b) (4), (b) (6) | 13 Oct 2020 08:01:11 |
| Query 'Per DM CLR: Please note this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components. ' answered with 'data updated' (Site from DM). | (b) (4), (b) (6) | 10 Oct 2020 13:51:21 |
| User entered '150/12.5' reason for change: Data Entry Error | (b) (4), (b) (6) | 10 Oct 2020 13:51:08 |
| User opened query 'Per DM CLR: Please note this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components. ' (Site from DM). | (b) (4), (b) (6) | 03 Oct 2020 05:55:18 |
| User entered '150' | (b) (4), (b) (6) | 13 Sep 2020 17:13:13 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:21:23

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:06:31 |
| User signature succeeded. | Terry Poling (b) (4) | 16 Apr 2021 15:55:48 |
| User entered 'mg (mg)' | (b) (4) (b) (4), (b) (6) | 13 Sep 2020 17:13:13 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:21:23

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:06:31 |
| User signature succeeded. | Terry Poling (b) (4) | 16 Apr 2021 15:55:48 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 13 Sep 2020 17:13:13 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:21:23

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:06:31 |
| User signature succeeded. | Terry Poling (b) (4) | 16 Apr 2021 15:55:48 |
| User entered 'once daily (QD)' | (b) (4) (b) (4), (b) (6) | 13 Sep 2020 17:13:13 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:21:23

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:06:31 |
| User signature succeeded. | Terry Poling (b) (4) | 16 Apr 2021 15:55:48 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 13 Sep 2020 17:13:13 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:21:23

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:06:31 |
| User signature succeeded. | Terry Poling (b) (4) | 16 Apr 2021 15:55:48 |
| User entered 'Oral (ORAL)' | (b) (4) (b) (4), (b) (6) | 13 Sep 2020 17:13:13 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:21:23

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:06:31 |
| User signature succeeded. | Terry Poling (b) (4) | 16 Apr 2021 15:55:48 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 13 Sep 2020 17:13:13 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:21:23

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:06:31 |
| User signature succeeded. | Terry Poling (b) (4) | 16 Apr 2021 15:55:48 |
| User entered 'un Jan 2017' | (b) (4) (b) (4), (b) (6) | 13 Sep 2020 17:13:13 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:21:23

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:06:31 |
| User signature succeeded. | Terry Poling (b) (4) | 16 Apr 2021 15:55:48 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 13 Sep 2020 17:13:13 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:21:23

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:06:31 |
| User signature succeeded. | Terry Poling (b) (4) | 16 Apr 2021 15:55:48 |
| User entered 'No (N)' reason for change: Data Entry Error | (b) (4) (b) (4), (b) (6) | 28 Jan 2021 21:28:47 |
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 13 Sep 2020 17:13:13 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:21:23

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:06:31 |
| User signature succeeded. | Terry Poling (b) (4) | 16 Apr 2021 15:55:48 |
| User entered '05 Nov 2020' reason for change: Data Entry Error | (b) (4), (b) (6) | 29 Jan 2021 21:50:39 |
| User entered '06 Nov 2020' reason for change: Data Entry Error | (b) (4), (b) (6) | 28 Jan 2021 21:28:47 |
| User entered empty. | (b) (4), (b) (6) | 13 Sep 2020 17:13:13 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:21:23

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:06:31 |
| User signature succeeded. | Terry Poling (b) (4) | 16 Apr 2021 15:55:48 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 13 Sep 2020 17:13:13 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:21:23

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:06:31 |
| User entered 'I' | System | 13 Sep 2020 17:13:13 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:21:23

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:06:31 |
| User entered 'I' | System | 13 Sep 2020 17:13:13 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:21:23

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:06:31 |
| User entered '804 (804)' | System | 13 Sep 2020 17:13:13 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:21:23

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:06:34 |
| User signature succeeded. | Terry Poling (b) (4) | 16 Apr 2021 15:55:48 |
| User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003. | (b) (4) Coder Import (b) (4) (b) (4) | 14 Sep 2020 03:51:38 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 14 Sep 2020 03:51:38 |
| Data point term sent to Coder | System | 13 Sep 2020 17:25:01 |
| User entered 'ibuprofen' | (b) (4), (b) (6) | 13 Sep 2020 17:24:46 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:21:23

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:06:34 |
| User signature succeeded. | Terry Poling (b) (4) | 16 Apr 2021 15:55:48 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 13 Sep 2020 17:24:46 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:21:23

[Indication](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:06:34 |
| User signature succeeded. | Terry Poling (b) (4) | 16 Apr 2021 15:55:48 |
| User entered 'pain, fever' | (b) (4) (b) (4), (b) (6) | 13 Sep 2020 17:24:46 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:21:23

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:06:34 |
| User signature succeeded. | Terry Poling (b) (4) | 16 Apr 2021 15:55:48 |
| User entered '400' | (b) (4) (b) (4), (b) (6) | 13 Sep 2020 17:24:46 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:21:23

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:06:34 |
| User signature succeeded. | Terry Poling (b) (4) | 16 Apr 2021 15:55:48 |
| User entered 'mg (mg)' | (b) (4) (b) (4), (b) (6) | 13 Sep 2020 17:24:46 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:21:23

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:06:34 |
| User signature succeeded. | Terry Poling (b) (4) | 16 Apr 2021 15:55:48 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 13 Sep 2020 17:24:46 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:21:23

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:06:34 |
| User signature succeeded. | Terry Poling (b) (4) | 16 Apr 2021 15:55:48 |
| User entered 'as needed (PRN)' | (b) (4) (b) (4), (b) (6) | 13 Sep 2020 17:24:46 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:21:23

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:06:34 |
| User signature succeeded. | Terry Poling (b) (4) | 16 Apr 2021 15:55:48 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 13 Sep 2020 17:24:46 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:21:23

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:06:34 |
| User signature succeeded. | Terry Poling (b) (4) | 16 Apr 2021 15:55:48 |
| User entered 'Oral (ORAL)' | (b) (4) (b) (4), (b) (6) | 13 Sep 2020 17:24:46 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:21:23

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:06:34 |
| User signature succeeded. | Terry Poling (b) (4) | 16 Apr 2021 15:55:48 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 13 Sep 2020 17:24:46 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:21:23

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:06:34 |
| User signature succeeded. | Terry Poling (b) (4) | 16 Apr 2021 15:55:48 |
| User entered '22 Aug 2020' | (b) (4) (b) (4), (b) (6) | 13 Sep 2020 17:24:46 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:21:23

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:06:34 |
| User signature succeeded. | Terry Poling (b) (4) | 16 Apr 2021 15:55:48 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 13 Sep 2020 17:24:46 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:21:23

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:06:34 |
| User signature succeeded. | Terry Poling (b) (4) | 16 Apr 2021 15:55:48 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 13 Sep 2020 17:24:46 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:21:23

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:06:34 |
| User signature succeeded. | Terry Poling (b) (4) | 16 Apr 2021 15:55:48 |
| User entered '22 Aug 2020' | (b) (4) (b) (4), (b) (6) | 13 Sep 2020 17:24:46 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:21:23

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:06:34 |
| User signature succeeded. | Terry Poling (b) (4) | 16 Apr 2021 15:55:48 |
| User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the PAIN, FEVER is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of PAIN, FEVER did not meet the AE reporting criteria. | (b) (4) (b) (4), (b) (6) | 13 Oct 2020 07:07:00 |
| ' (Site from DM). | | |
| Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the PAIN, FEVER is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of PAIN, FEVER did not meet the AE reporting criteria. | (b) (4), (b) (6) | 08 Oct 2020 14:55:09 |
| ' answered with 'Confirm does not meet reporting criteria' (Site from DM). | | |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:21:23

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the PAIN, FEVER is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of PAIN, FEVER did not meet the AE reporting criteria. ' (Site from DM). User entered 'Yes (Y)' | (b) (4), (b) (6) | 03 Oct 2020 05:55:53 |
| | (b) (4), (b) (6) | 13 Sep 2020 17:24:46 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:21:23

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:06:34 |
| User entered empty. | System | 13 Sep 2020 17:24:46 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:21:23

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:06:34 |
| User entered empty. | System | 13 Sep 2020 17:24:46 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:21:23

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:06:34 |
| User entered empty. | System | 13 Sep 2020 17:24:46 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:21:23

[Name of Medication](#)

| Audit | User | Time (GMT) |
|---|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:06:38 |
| User signature succeeded. | Terry Poling (b) (4) | 16 Apr 2021 15:55:48 |
| User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: NITROFURAN DERIVATIVES, PRODUCT: NITROFURANTOIN - version WHODrug-Global-B3\\202003. | (b) (4) Coder Import (b) (4) (b) (4) | 01 Oct 2020 22:49:01 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) (b) (4) | 01 Oct 2020 22:49:01 |
| Data point term sent to Coder | System | 01 Oct 2020 22:47:29 |
| User entered 'nitrofurantoin' | (b) (4), (b) (6) | 01 Oct 2020 22:47:17 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:21:23

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:06:38 |
| User signature succeeded. | Terry Poling (b) (4) | 16 Apr 2021 15:55:48 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 01 Oct 2020 22:47:17 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:21:23

[Indication](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:06:38 |
| User signature succeeded. | Terry Poling (b) (4) | 16 Apr 2021 15:55:48 |
| User entered 'urinary tract infection' | (b) (4) (b) (4), (b) (6) | 01 Oct 2020 22:47:17 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:21:23

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:06:38 |
| User signature succeeded. | Terry Poling (b) (4) | 16 Apr 2021 15:55:48 |
| User entered '100' | (b) (4) (b) (4), (b) (6) | 01 Oct 2020 22:47:17 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:21:23

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:06:38 |
| User signature succeeded. | Terry Poling (b) (4) | 16 Apr 2021 15:55:48 |
| User entered 'mg (mg)' | (b) (4) (b) (4), (b) (6) | 01 Oct 2020 22:47:17 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:21:23

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:06:38 |
| User signature succeeded. | Terry Poling (b) (4) | 16 Apr 2021 15:55:48 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 01 Oct 2020 22:47:17 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:21:23

[Frequency](#)

| Audit | User | Time (GMT) |
|----------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:06:38 |
| User signature succeeded. | Terry Poling (b) (4) | 16 Apr 2021 15:55:48 |
| User entered 'twice daily (BID)' | (b) (4) (b) (4), (b) (6) | 01 Oct 2020 22:47:17 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:21:23

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:06:38 |
| User signature succeeded. | Terry Poling (b) (4) | 16 Apr 2021 15:55:48 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 01 Oct 2020 22:47:17 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:21:23

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:06:38 |
| User signature succeeded. | Terry Poling (b) (4) | 16 Apr 2021 15:55:48 |
| User entered 'Oral (ORAL)' | (b) (4) (b) (4), (b) (6) | 01 Oct 2020 22:47:17 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:21:23

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:06:38 |
| User signature succeeded. | Terry Poling (b) (4) | 16 Apr 2021 15:55:48 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 01 Oct 2020 22:47:17 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:21:23

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:06:38 |
| User signature succeeded. | Terry Poling (b) (4) | 16 Apr 2021 15:55:48 |
| User entered '22 Aug 2020' | (b) (4) (b) (4), (b) (6) | 01 Oct 2020 22:47:17 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:21:23

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:06:38 |
| User signature succeeded. | Terry Poling (b) (4) | 16 Apr 2021 15:55:48 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 01 Oct 2020 22:47:17 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:21:23

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:06:38 |
| User signature succeeded. | Terry Poling (b) (4) | 16 Apr 2021 15:55:48 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 01 Oct 2020 22:47:17 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:21:23

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:06:38 |
| User signature succeeded. | Terry Poling (b) (4) | 16 Apr 2021 15:55:48 |
| User entered '26 Aug 2020' | (b) (4) (b) (4), (b) (6) | 01 Oct 2020 22:47:17 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:21:23

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:06:38 |
| User signature succeeded. | Terry Poling (b) (4) | 16 Apr 2021 15:55:48 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 01 Oct 2020 22:47:17 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:21:23

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:06:38 |
| User entered '2' | System | 01 Oct 2020 22:47:17 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:21:23

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:06:38 |
| User entered 'I' | System | 01 Oct 2020 22:47:17 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:21:23

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:06:38 |
| User entered '804 (804)' | System | 01 Oct 2020 22:47:17 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:21:23

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| User signature succeeded. | Terry Poling (b) (4) | 16 Apr 2021 15:55:48 |
| User closed query 'Per DM CLR: Please review the start/stop date of this medication as it overlaps with Con Med name, #6 IRBESARTAN HYDROCHLOROTHIAZIDE (UN JAN 2017-Ongoing). Please consider updating dates if necessary or review if this is a duplicate. Update Con Med eCRF as appropriate.' (Site from DM). Query 'Per DM CLR: Please review the start/stop date of this medication as it overlaps with Con Med name, #6 IRBESARTAN HYDROCHLOROTHIAZIDE (UN JAN 2017-Ongoing). Please consider updating dates if necessary or review if this is a duplicate. Update Con Med eCRF as appropriate.' answered with 'stop date updated ' (Site from DM). | (b) (4), (b) (6) | 01 Feb 2021 10:08:29 |
| User opened query 'Per DM CLR: Please review the start/stop date of this medication as it overlaps with Con Med name, #6 IRBESARTAN HYDROCHLOROTHIAZIDE (UN JAN 2017-Ongoing). Please consider updating dates if necessary or review if this is a duplicate. Update Con Med eCRF as appropriate.' (Site from DM). | (b) (4), (b) (6) | 29 Jan 2021 21:50:24 |
| User opened query 'Per DM CLR: Please review the start/stop date of this medication as it overlaps with Con Med name, #6 IRBESARTAN HYDROCHLOROTHIAZIDE (UN JAN 2017-Ongoing). Please consider updating dates if necessary or review if this is a duplicate. Update Con Med eCRF as appropriate.' (Site from DM). | (b) (4), (b) (6) | 05 Jan 2021 06:19:28 |
| User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), COMBINATIONS, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS) AND DIURETICS, PRODUCT: HYDROCHLOROTHIAZIDE;IRBESARTAN, PRODUCTSYNONYM: IRBESARTAN HCTZ - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 11 Nov 2020 16:05:34 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 11 Nov 2020 16:05:34 |
| Data point term sent to Coder | System | 11 Nov 2020 15:49:13 |
| User entered 'Irbesartan/HCTZ' | (b) (4), (b) (6) | 11 Nov 2020 15:48:38 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:21:23

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Terry Poling (b) (4) | 16 Apr 2021 15:55:48 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 15:48:38 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:21:23

[Indication](#)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| User signature succeeded. | Terry Poling (b) (4) | 16 Apr 2021 15:55:48 |
| User closed query 'Per DM CLR: Was the dose of this medication increased because the patient experienced a worsening or exacerbation of the medical history condition/ adverse event being treated? If yes, please add the worsening AE and applicable data to the AE eCRF or provide explanation for addition of new medication.' (Site from DM). | (b) (4) (b) (4), (b) (6) | 01 Feb 2021 10:08:33 |
| Query 'Per DM CLR: Was the dose of this medication increased because the patient experienced a worsening or exacerbation of the medical history condition/ adverse event being treated? If yes, please add the worsening AE and applicable data to the AE eCRF or provide explanation for addition of new medication.' answered with 'not a WORSENING ' (Site from DM). | (b) (4), (b) (6) | 28 Jan 2021 21:27:23 |
| User opened query 'Per DM CLR: Was the dose of this medication increased because the patient experienced a worsening or exacerbation of the medical history condition/ adverse event being treated? If yes, please add the worsening AE and applicable data to the AE eCRF or provide explanation for addition of new medication.' (Site from DM). | (b) (4), (b) (6) | 05 Jan 2021 06:18:37 |
| User entered 'hypertension' | (b) (4), (b) (6) | 11 Nov 2020 15:48:38 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:21:23

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| User signature succeeded. | Terry Poling (b) (4) | 16 Apr 2021 15:55:48 |
| User closed query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable (e.g., 300/12.5mg).' (Site from DM). | (b) (4) (b) (4), (b) (6) | 01 Feb 2021 20:02:50 |
| User entered '300' reason for change: Data Entry Error | (b) (4), (b) (6) | 28 Jan 2021 21:28:05 |
| Query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable (e.g., 300/12.5mg).' answered with 'updated' (Site from DM). | (b) (4), (b) (6) | 28 Jan 2021 21:26:49 |
| User entered '150' reason for change: Data Entry Error | (b) (4), (b) (6) | 28 Jan 2021 21:26:40 |
| User opened query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable (e.g., 300/12.5mg).' (Site from DM). | (b) (4), (b) (6) | 05 Jan 2021 06:18:52 |
| User entered '300' | (b) (4), (b) (6) | 11 Nov 2020 15:48:38 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:21:23

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Terry Poling (b) (4) | 16 Apr 2021 15:55:48 |
| User entered 'mg (mg)' | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 15:48:38 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:21:23

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Terry Poling (b) (4) | 16 Apr 2021 15:55:48 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 15:48:38 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:21:23

[Frequency](#)

| Audit | User | Time (GMT) |
|----------------------------------|-----------------------------|----------------------|
| User signature succeeded. | Terry Poling (b) (4) | 16 Apr 2021 15:55:48 |
| User entered 'twice daily (BID)' | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 15:48:38 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:21:23

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Terry Poling (b) (4) | 16 Apr 2021 15:55:48 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 15:48:38 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:21:23

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded. | Terry Poling (b) (4) | 16 Apr 2021 15:55:48 |
| User entered 'Oral (ORAL)' | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 15:48:38 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:21:23

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Terry Poling (b) (4) | 16 Apr 2021 15:55:48 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 15:48:38 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:21:23

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|----------------------|----------------------|
| User signature succeeded. | Terry Poling (b) (4) | 16 Apr 2021 15:55:48 |
| User entered '6 Nov 2020' reason for change: Data Entry Error | (b) (4) | |
| | (b) (4), (b) (6) | 29 Jan 2021 21:50:50 |
| User entered '5 Nov 2020' reason for change: Data Entry Error | (b) (4), (b) (6) | 29 Jan 2021 21:50:15 |
| User entered '6 Nov 2020' | (b) (4), (b) (6) | 11 Nov 2020 15:48:38 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:21:23

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Terry Poling (b) (4) | 16 Apr 2021 15:55:48 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 15:48:38 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:21:23

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Terry Poling (b) (4) | 16 Apr 2021 15:55:48 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 15:48:38 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:21:23

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Terry Poling (b) (4) | 16 Apr 2021 15:55:48 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 15:48:38 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:21:23

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Terry Poling (b) (4) | 16 Apr 2021 15:55:48 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 15:48:38 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:21:23

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '2' | System | 11 Nov 2020 15:48:38 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:21:23

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 11 Nov 2020 15:48:38 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:21:23

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 11 Nov 2020 15:48:38 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:21:23

[Name of Medication](#)

| Audit | User | Time (GMT) |
|---|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:06:42 |
| User signature succeeded. | Terry Poling (b) (4) | 16 Apr 2021 15:55:48 |
| User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 11 Nov 2020 15:52:33 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 11 Nov 2020 15:52:33 |
| Data point term sent to Coder | System | 11 Nov 2020 15:51:17 |
| User entered 'influenza vaccine' | (b) (4), (b) (6) | 11 Nov 2020 15:50:21 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:21:23

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:06:42 |
| User signature succeeded. | Terry Poling (b) (4) | 16 Apr 2021 15:55:48 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 15:50:21 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:21:23

[Indication](#)

| Audit | User | Time (GMT) |
|--------------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:06:42 |
| User signature succeeded. | Terry Poling (b) (4) | 16 Apr 2021 15:55:48 |
| User entered 'influenza prophylaxis' | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 15:50:21 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:21:23

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:06:42 |
| User signature succeeded. | Terry Poling (b) (4) | 16 Apr 2021 15:55:48 |
| User entered '0.5' | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 15:50:21 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:21:23

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:06:42 |
| User signature succeeded. | Terry Poling (b) (4) | 16 Apr 2021 15:55:48 |
| User entered 'mL (mL)' | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 15:50:21 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:21:23

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:06:42 |
| User signature succeeded. | Terry Poling (b) (4) | 16 Apr 2021 15:55:48 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 15:50:21 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:21:23

[Frequency](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:06:42 |
| User signature succeeded. | Terry Poling (b) (4) | 16 Apr 2021 15:55:48 |
| User entered 'once (ONCE)' | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 15:50:21 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:21:23

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:06:42 |
| User signature succeeded. | Terry Poling (b) (4) | 16 Apr 2021 15:55:48 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 15:50:21 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:21:23

[Route of administration](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:06:42 |
| User signature succeeded. | Terry Poling (b) (4) | 16 Apr 2021 15:55:48 |
| User entered 'Intramuscular (INTRAMUSCULAR)' | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 15:50:21 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:21:23

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:06:42 |
| User signature succeeded. | Terry Poling (b) (4) | 16 Apr 2021 15:55:48 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 15:50:21 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:21:23

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:06:42 |
| User signature succeeded. | Terry Poling (b) (4) | 16 Apr 2021 15:55:48 |
| User entered '15 Oct 2020' | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 15:50:21 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:21:23

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:06:42 |
| User signature succeeded. | Terry Poling (b) (4) | 16 Apr 2021 15:55:48 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 15:50:21 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:21:23

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:06:42 |
| User signature succeeded. | Terry Poling (b) (4) | 16 Apr 2021 15:55:48 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 15:50:21 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:21:23

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:06:42 |
| User signature succeeded. | Terry Poling (b) (4) | 16 Apr 2021 15:55:48 |
| User entered '15 Oct 2020' | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 15:50:21 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:21:23

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:06:42 |
| User signature succeeded. | Terry Poling (b) (4) | 16 Apr 2021 15:55:48 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 11 Nov 2020 15:50:21 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:21:23

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:06:42 |
| User entered empty. | System | 11 Nov 2020 15:50:21 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:21:23

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:06:42 |
| User entered empty. | System | 11 Nov 2020 15:50:21 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:21:23

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:06:42 |
| User entered empty. | System | 11 Nov 2020 15:50:21 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:21:23

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--|----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:16:22 |
| User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: HYDROCODONE BITARTRATE;PARACETAMOL, PRODUCTSYNONYM: NORCO - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 30 Apr 2021 17:17:08 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 30 Apr 2021 17:17:08 |
| User signature succeeded. | Terry Poling (b) (4) | 30 Apr 2021 15:49:11 |
| Data point term sent to Coder | System | 30 Apr 2021 14:27:12 |
| User entered 'Norco [Hydrocodone 5mg/acetaminophen325mg]' | (b) (4), (b) (6) | 30 Apr 2021 14:26:22 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:21:23

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:16:22 |
| User signature succeeded. | Terry Poling (b) (4) | 30 Apr 2021 15:49:11 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 30 Apr 2021 14:26:22 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:21:23

[Indication](#)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:16:22 |
| User signature succeeded. | Terry Poling (b) (4) | 30 Apr 2021 15:49:11 |
| User entered 'atypical complex hyperplasia' | (b) (4) (b) (4), (b) (6) | 30 Apr 2021 14:26:22 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:21:23

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:16:22 |
| User signature succeeded. | Terry Poling (b) (4) | 30 Apr 2021 15:49:11 |
| User entered '5/325' | (b) (4) (b) (4), (b) (6) | 30 Apr 2021 14:26:22 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:21:23

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:16:22 |
| User signature succeeded. | Terry Poling (b) (4) | 30 Apr 2021 15:49:11 |
| User entered 'mg (mg)' | (b) (4) (b) (4), (b) (6) | 30 Apr 2021 14:26:22 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:21:23

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:16:22 |
| User signature succeeded. | Terry Poling (b) (4) | 30 Apr 2021 15:49:11 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 30 Apr 2021 14:26:22 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:21:23

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:16:22 |
| User signature succeeded. | Terry Poling (b) (4) | 30 Apr 2021 15:49:11 |
| User entered 'as needed (PRN)' | (b) (4) (b) (4), (b) (6) | 30 Apr 2021 14:26:22 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:21:23

If frequency is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:16:22 |
| User signature succeeded. | Terry Poling (b) (4) | 30 Apr 2021 15:49:11 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 30 Apr 2021 14:26:22 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:21:23

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:16:22 |
| User signature succeeded. | Terry Poling (b) (4) | 30 Apr 2021 15:49:11 |
| User entered 'Oral (ORAL)' | (b) (4) (b) (4), (b) (6) | 30 Apr 2021 14:26:22 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:21:23

[If route of administration is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:16:22 |
| User signature succeeded. | Terry Poling (b) (4) | 30 Apr 2021 15:49:11 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 30 Apr 2021 14:26:22 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:21:23

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:16:22 |
| User signature succeeded. | Terry Poling (b) (4) | 30 Apr 2021 15:49:11 |
| User entered '16 Mar 2021' | (b) (4) (b) (4), (b) (6) | 30 Apr 2021 14:26:22 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:21:23

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:16:22 |
| User signature succeeded. | Terry Poling (b) (4) | 30 Apr 2021 15:49:11 |
| User entered '0' | (b) (4) (b) (4), (b) (6) | 30 Apr 2021 14:26:22 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:21:23

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:16:22 |
| User signature succeeded. | Terry Poling (b) (4) | 30 Apr 2021 15:49:11 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 30 Apr 2021 14:26:22 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:21:23

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:16:22 |
| User signature succeeded. | Terry Poling (b) (4) | 30 Apr 2021 15:49:11 |
| User entered '18 Mar 2021' | (b) (4) (b) (4), (b) (6) | 30 Apr 2021 14:26:22 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:21:23

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:16:22 |
| User signature succeeded. | Terry Poling (b) (4) | 30 Apr 2021 15:49:11 |
| User entered 'No (N)' | (b) (4) (b) (4), (b) (6) | 30 Apr 2021 14:26:22 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:21:23

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:16:22 |
| User entered empty. | System | 30 Apr 2021 14:26:22 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:21:23

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:16:22 |
| User entered empty. | System | 30 Apr 2021 14:26:22 |

US3592229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:21:23

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:16:22 |
| User entered empty. | System | 30 Apr 2021 14:26:22 |

US3592229

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 08:21:23

[Were any concomitant procedures performed?](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 03:45:23 |
| User signature succeeded. | Terry Poling (b) (4) | 03 May 2021 19:54:33 |
| User closed query 'Per ETRTR: According to SAE page "Atypical Complex Hyperplasia", ConProcedure action was taken for SAE, but the same is missing in this folder. Please add Concomitant Procedure details for SAE or reconcile otherwise, thanks.' (Site from CRA). | (b) (4) (b) (4), (b) (6) | 03 May 2021 12:39:16 |
| Query 'Per ETRTR: According to SAE page "Atypical Complex Hyperplasia", ConProcedure action was taken for SAE, but the same is missing in this folder. Please add Concomitant Procedure details for SAE or reconcile otherwise, thanks.' answered with 'updated page' (Site from CRA). | (b) (4), (b) (6) | 30 Apr 2021 14:23:20 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | (b) (4), (b) (6) | 30 Apr 2021 14:23:10 |
| User opened query 'Per ETRTR: According to SAE page "Atypical Complex Hyperplasia", ConProcedure action was taken for SAE, but the same is missing in this folder. Please add Concomitant Procedure details for SAE or reconcile otherwise, thanks.' (Site from CRA). | (b) (4), (b) (6) | 23 Mar 2021 22:48:01 |
| User entered 'No (N)' | (b) (4), (b) (6) | 03 Sep 2020 17:47:19 |

US3592229

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:21:23

Procedure/Surgery date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded. | Terry Poling (b) (4) | 30 Apr 2021 15:49:11 |
| User entered '16 Mar 2021' | (b) (4) (b) (4), (b) (6) | 30 Apr 2021 14:29:10 |

US3592229

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:21:23

[Procedure/Surgery](#)

| Audit | User | Time (GMT) |
|-----------------------------|-----------------------------|----------------------|
| User signature succeeded. | Terry Poling (b) (4) | 30 Apr 2021 15:49:11 |
| User entered 'Hysterectomy' | (b) (4) (b) (4), (b) (6) | 30 Apr 2021 14:29:10 |

US3592229

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:21:23

[Indication](#)

| Audit | User | Time (GMT) |
|-----------------------------------|-----------------------------|----------------------|
| User signature succeeded. | Terry Poling (b) (4) | 30 Apr 2021 15:49:11 |
| User entered 'Adverse Event (AE)' | (b) (4) (b) (4), (b) (6) | 30 Apr 2021 14:29:10 |

US3592229

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:21:23

[If indication is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Terry Poling (b) (4) | 30 Apr 2021 15:49:11 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 30 Apr 2021 14:29:10 |

US3592229

Folder: SAE USA-US103-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:21:23

[SAEID](#)

| Audit | User | Time (GMT) |
|---|----------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 30 Apr 2021 19:27:25 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:37:55 |
| User entered 'USA-US103-2021-MRNA-1273-P301000006' | (b) (4) System | 22 Mar 2021 18:06:30 |

US3592229

Folder: SAE USA-US103-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:21:23

Serious

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 30 Apr 2021 19:27:25 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:37:55 |
| User entered 'Yes (Y)' | (b) (4) System | 22 Mar 2021 18:06:30 |

US3592229

Folder: SAE USA-US103-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:21:23

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 30 Apr 2021 19:27:25 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:37:55 |
| User entered 'No (N)' | (b) (4) System | 22 Mar 2021 18:06:30 |

US3592229

Folder: SAE USA-US103-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:21:23

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 30 Apr 2021 19:27:25 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:37:55 |
| User entered 'No (N)' | (b) (4) System | 22 Mar 2021 18:06:30 |

US3592229

Folder: SAE USA-US103-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:21:23

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 30 Apr 2021 19:27:25 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:37:55 |
| User entered 'Yes (Y)' | (b) (4) System | 22 Mar 2021 18:06:30 |

US3592229

Folder: SAE USA-US103-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:21:23

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 30 Apr 2021 19:27:25 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:37:55 |
| User entered 'No (N)' | (b) (4) System | 22 Mar 2021 18:06:30 |

US3592229

Folder: SAE USA-US103-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:21:23

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 30 Apr 2021 19:27:25 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:37:55 |
| User entered 'No (N)' | (b) (4) System | 22 Mar 2021 18:06:30 |

US3592229

Folder: SAE USA-US103-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:21:23

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 30 Apr 2021 19:27:25 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:37:55 |
| User entered 'No (N)' | (b) (4) System | 22 Mar 2021 18:06:30 |

US3592229

Folder: SAE USA-US103-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:21:23

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 30 Apr 2021 19:27:25 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:37:55 |
| User entered 'Terry' | (b) (4) System | 22 Mar 2021 18:06:30 |

US3592229

Folder: SAE USA-US103-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:21:23

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 30 Apr 2021 19:27:25 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:37:55 |
| User entered 'Poling' | (b) (4) System | 22 Mar 2021 18:06:30 |

US3592229

Folder: SAE USA-US103-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:21:23

Site Address: [Street](#)

| Audit | User | Time (GMT) |
|-------------------------------|----------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 30 Apr 2021 19:27:25 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:37:55 |
| User entered '1709 S Rock Rd' | (b) (4) System | 22 Mar 2021 18:06:30 |

US3592229

Folder: SAE USA-US103-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:21:23

Site Address: [City](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 30 Apr 2021 19:27:25 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:37:55 |
| User entered 'Wichita' | (b) (4) System | 22 Mar 2021 18:06:30 |

US3592229

Folder: SAE USA-US103-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:21:23

[Site Address: State](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 30 Apr 2021 19:27:25 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:37:55 |
| User entered 'KS' | (b) (4) System | 22 Mar 2021 18:06:30 |

US3592229

Folder: SAE USA-US103-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:21:23

[Site Address: Postal Code](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 30 Apr 2021 19:27:25 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:37:55 |
| User entered '67207' | (b) (4) System | 22 Mar 2021 18:06:30 |

US3592229

Folder: SAE USA-US103-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:21:23

[Investigator Country](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 30 Apr 2021 19:27:25 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:37:55 |
| User entered 'US' | (b) (4) System | 22 Mar 2021 18:07:12 |

US3592229

Folder: SAE USA-US103-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:21:23

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '2' | System | 30 Apr 2021 19:28:04 |
| User entered '1' | System | 22 Mar 2021 18:07:12 |

US3592229

Folder: SAE USA-US103-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:21:23

[SAEID](#)

| Audit | User | Time (GMT) |
|---|----------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 30 Apr 2021 19:27:25 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:37:55 |
| User entered 'USA-US103-2021-MRNA-1273-P301000006' | (b) (4) System | 22 Mar 2021 18:06:30 |

US3592229

Folder: SAE USA-US103-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:21:23

Serious

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 30 Apr 2021 19:27:25 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:37:55 |
| User entered 'Yes (Y)' | (b) (4) System | 22 Mar 2021 18:06:30 |

US3592229

Folder: SAE USA-US103-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:21:23

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 30 Apr 2021 19:27:25 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:37:55 |
| User entered 'No (N)' | (b) (4) System | 22 Mar 2021 18:06:30 |

US3592229

Folder: SAE USA-US103-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:21:23

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 30 Apr 2021 19:27:25 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:37:55 |
| User entered 'No (N)' | (b) (4) System | 22 Mar 2021 18:06:30 |

US3592229

Folder: SAE USA-US103-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:21:23

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 30 Apr 2021 19:27:25 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:37:55 |
| User entered 'Yes (Y)' | (b) (4) System | 22 Mar 2021 18:06:30 |

US3592229

Folder: SAE USA-US103-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:21:23

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 30 Apr 2021 19:27:25 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:37:55 |
| User entered 'No (N)' | (b) (4) System | 22 Mar 2021 18:06:30 |

US3592229

Folder: SAE USA-US103-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:21:23

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 30 Apr 2021 19:27:25 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:37:55 |
| User entered 'No (N)' | (b) (4) System | 22 Mar 2021 18:06:30 |

US3592229

Folder: SAE USA-US103-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:21:23

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 30 Apr 2021 19:27:25 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:37:55 |
| User entered 'No (N)' | (b) (4) System | 22 Mar 2021 18:06:30 |

US3592229

Folder: SAE USA-US103-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:21:23

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 30 Apr 2021 19:27:25 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:37:55 |
| User entered 'Terry' | (b) (4) System | 22 Mar 2021 18:06:30 |

US3592229

Folder: SAE USA-US103-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:21:23

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 30 Apr 2021 19:27:25 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:37:55 |
| User entered 'Poling' | (b) (4) System | 22 Mar 2021 18:06:30 |

US3592229

Folder: SAE USA-US103-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:21:23

[Site Address: Street](#)

| Audit | User | Time (GMT) |
|-------------------------------|----------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 30 Apr 2021 19:27:25 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:37:55 |
| User entered '1709 S Rock Rd' | (b) (4) System | 22 Mar 2021 18:06:30 |

US3592229

Folder: SAE USA-US103-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:21:23

[Site Address: City](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 30 Apr 2021 19:27:25 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:37:55 |
| User entered 'Wichita' | (b) (4) System | 22 Mar 2021 18:06:30 |

US3592229

Folder: SAE USA-US103-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:21:23

[Site Address: State](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 30 Apr 2021 19:27:25 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:37:55 |
| User entered 'KS' | (b) (4) System | 22 Mar 2021 18:06:30 |

US3592229

Folder: SAE USA-US103-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:21:23

[Site Address: Postal Code](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 30 Apr 2021 19:27:25 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:37:55 |
| User entered '67207' | (b) (4) System | 22 Mar 2021 18:06:30 |

US3592229

Folder: SAE USA-US103-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:21:23

[Investigator Country](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 30 Apr 2021 19:27:25 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:37:55 |
| User entered 'US' | (b) (4) System | 22 Mar 2021 18:07:12 |

US3592229

Folder: SAE USA-US103-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:21:23

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '2' | System | 30 Apr 2021 19:28:04 |
| User entered '1' | System | 22 Mar 2021 18:07:12 |

US3592229

Folder: SAE USA-US103-2021-MRNA-1273-P301000006

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 08:21:23

[Date of submission \(Pre-filled from custom function\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------|----------------------|
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:37:55 |
| User entered '22/Mar/2021 11:07' | (b) (4) System | 22 Mar 2021 18:07:12 |

US3592229

Folder: SAE USA-US103-2021-MRNA-1273-P301000006

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 08:21:23

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 30 Apr 2021 19:27:25 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:37:55 |
| User entered 'I' | (b) (4) (b) (4), (b) (6) | 22 Mar 2021 18:07:12 |

US3592229

Folder: SAE USA-US103-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:21:23

[SAEID](#)

| Audit | User | Time (GMT) |
|---|----------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 30 Apr 2021 19:27:25 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:37:55 |
| User entered 'USA-US103-2021-MRNA-1273-P301000006' | (b) (4) System | 22 Mar 2021 18:06:30 |

US3592229

Folder: SAE USA-US103-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:21:23

Serious

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 30 Apr 2021 19:27:25 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:37:55 |
| User entered 'Yes (Y)' | (b) (4) System | 22 Mar 2021 18:06:30 |

US3592229

Folder: SAE USA-US103-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:21:23

Death

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 30 Apr 2021 19:27:25 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:37:55 |
| User entered 'No (N)' | (b) (4) System | 22 Mar 2021 18:06:30 |

US3592229

Folder: SAE USA-US103-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:21:23

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 30 Apr 2021 19:27:25 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:37:55 |
| User entered 'No (N)' | (b) (4) System | 22 Mar 2021 18:06:30 |

US3592229

Folder: SAE USA-US103-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:21:23

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 30 Apr 2021 19:27:25 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:37:55 |
| User entered 'Yes (Y)' | (b) (4) System | 22 Mar 2021 18:06:30 |

US3592229

Folder: SAE USA-US103-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:21:23

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 30 Apr 2021 19:27:25 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:37:55 |
| User entered 'No (N)' | (b) (4) System | 22 Mar 2021 18:06:30 |

US3592229

Folder: SAE USA-US103-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:21:23

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 30 Apr 2021 19:27:25 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:37:55 |
| User entered 'No (N)' | (b) (4) System | 22 Mar 2021 18:06:30 |

US3592229

Folder: SAE USA-US103-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:21:23

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 30 Apr 2021 19:27:25 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:37:55 |
| User entered 'No (N)' | (b) (4) System | 22 Mar 2021 18:06:30 |

US3592229

Folder: SAE USA-US103-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:21:23

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 30 Apr 2021 19:27:25 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:37:55 |
| User entered 'Terry' | (b) (4) System | 22 Mar 2021 18:06:30 |

US3592229

Folder: SAE USA-US103-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:21:23

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 30 Apr 2021 19:27:25 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:37:55 |
| User entered 'Poling' | (b) (4) System | 22 Mar 2021 18:06:30 |

US3592229

Folder: SAE USA-US103-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:21:23

[Site Address: Street](#)

| Audit | User | Time (GMT) |
|-------------------------------|----------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 30 Apr 2021 19:27:25 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:37:55 |
| User entered '1709 S Rock Rd' | (b) (4) System | 22 Mar 2021 18:06:30 |

US3592229

Folder: SAE USA-US103-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:21:23

[Site Address: City](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 30 Apr 2021 19:27:25 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:37:55 |
| User entered 'Wichita' | (b) (4) System | 22 Mar 2021 18:06:30 |

US3592229

Folder: SAE USA-US103-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:21:23

[Site Address: State](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 30 Apr 2021 19:27:25 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:37:55 |
| User entered 'KS' | (b) (4) System | 22 Mar 2021 18:06:30 |

US3592229

Folder: SAE USA-US103-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:21:23

[Site Address: Postal Code](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 30 Apr 2021 19:27:25 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:37:55 |
| User entered '67207' | (b) (4) System | 22 Mar 2021 18:06:30 |

US3592229

Folder: SAE USA-US103-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:21:23

[Investigator Country](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 30 Apr 2021 19:27:25 |
| User signature succeeded. | Terry Poling (b) (4) | 28 Apr 2021 09:37:55 |
| User entered 'US' | (b) (4) System | 22 Mar 2021 18:07:12 |

US3592229

Folder: SAE USA-US103-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 08:21:23

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '2' | System | 30 Apr 2021 19:28:04 |
| User entered '1' | System | 22 Mar 2021 18:07:12 |

US3592229

Folder: SAE USA-US103-2021-MRNA-1273-P301000006

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 08:21:23

[Date of submission \(Pre-filled from custom function\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|----------------------|----------------------|
| User signature succeeded. | Terry Poling (b) (4) | 03 May 2021 19:54:33 |
| User entered '30/Apr/2021 12:27' | (b) (4) System | 30 Apr 2021 19:28:04 |

US3592229

Folder: SAE USA-US103-2021-MRNA-1273-P301000006

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 08:21:23

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. | Terry Poling (b) (4) | 03 May 2021 19:54:33 |
| User entered 'I' | (b) (4) (b) (4), (b) (6) | 30 Apr 2021 19:28:04 |